UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	**MD-15-02641-PHX-DGC**
	Phoenix, Arizona
	May 31, 2018
Doris Jones, an individual,	
Plaintiff,	
v.	CV-16-00782-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 11

(Pages 2382 - 2508)

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

A P P E A R A N C E S

For Plaintiff:

Gallagher & Kennedy
By: **MARK S. O'CONNOR**, ESQ.
By: **PAUL L. STOLLER**, ESQ.
By: **SHANNON L. CLARK**, ESQ.
By: **C. LINCOLN COMBS**, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

Lopez McHugh, LLP
By: **RAMON ROSSI LOPEZ**, ESQ.
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660

Lopez McHugh, LLP
By: **JOSHUA MANKOFF**, ESQ.
214 Flynn Ave.
Moorestown, NJ 08057

Heaviside Reed Zaic
By: **JULIA REED ZAIC**, ESQ.
By: **LAURA E. SMITH**, ESQ.
312 Broadway, Ste. 203
Laguna Beach, CA 92651

For Defendants:

Nelson Mullins Riley & Scarborough
By: **RICHARD B. NORTH, JR.** ESQ.
By: **ELIZABETH C. HELM**, ESQ.
201 17th Street NW, Suite 1700
Atlanta, GA 30363

Nelson Mullins Riley & Scarborough.
BY: **JAMES F. ROGERS**, ESQ.
1320 Main St.
Columbia, SC 29201

Snell & Wilmer
By: **AMANDA C. SHERIDAN**, ESQ.
400 East Van Buren
Phoenix, AZ 85004

I N D E X

08:30:08

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

08:30:24

THE COURT: Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: Counsel, at the beginning of the trial I specifically asked both sides to make sure that you worked

08:30:49

with Traci to have all of the exhibits done by the end of the trial. We got to the end yesterday and found that many of them, maybe most of them, were not done. The redactions had not been made. There was no electronic version submitted in redacted form. And I'd specifically asked you to make sure

08:31:06

that got done.

Traci was here until 7 o'clock last night working with your staffs trying to get it done. It couldn't be finished by then. It's not done now.

That means we have exhibits that can't go to the jury

08:31:18

this morning in electronic form. And it's very frustrating that that happened when I specifically asked you to do that at the beginning of the trial.

It means that -- it may be we'll get a thumb drive before it goes to the jury that Traci can verify and send

08:31:35

back. If not, some of the exhibits cannot go in electronic

form and the jury's going to have a mix of the two that they'll have to sort through.

Next time, please pay attention to what I ask you to do, and make sure in the next four trials that all of the exhibits are done by the close of evidence so that we don't run into this problem again. It's not -- with this kind of staffing it's not a problem that we should be running into.

I also think you all should buy Traci a bouquet of flowers.

All right. Let's talk about jury instructions for a moment.

Going through the instructions that have been handed to you, I want to explain what we've done. On instruction number 12, we reordered the number of the claims so that we have the design defect claim and the negligent design claim next to each other since they're now linked in terms of the instruction. And we did the same thing in the verdict form. We reordered the numbers so that they are together so that we don't have the jury jumping over one before they're thinking about the fact that they have to decide this the same.

And we took out the last sentence of instruction 12 saying you should consider each claim separately as we're now telling them to consider two claims together.

On instruction number 14, we put in the language telling them to consider them together, but I concluded that

it should be at the beginning and not the end of the instruction. So it's been added to the first paragraph in instruction 14 and reworded a little bit from what was proposed. And also added to the first paragraph in instruction 15 using the same wording.

And I changed the language in the next-to-last paragraph in 15 just to be more specific in referring back to instruction 14 rather than simply saying "As I previously instructed you."

On instruction number 18, we made the change in the fifth paragraph that we talked about yesterday, although I added a few words to make the parenthetical make sense.

And we made the change that we also agreed to in the last paragraph.

On the paragraph at the bottom of the first page of instruction 18, I went with the plaintiff's proposal of more likely than not. And this is the reason: We went back and looked for the reasonable certainty language that's in the fourth paragraph, fifth paragraph. It's not in the Georgia standard instruction. And so I wondered where did that come from. And so we went back and it was actually language that was proposed by the parties in your original set of instructions in the Booker trial. That's how it got into the damages instructions.

So it wasn't the Georgia instructions that would have

08:34:40 required us to say reasonable certainty in the last paragraph on instruction 18, first page. We read the *Womack* case. It didn't talk about reasonable medical certainty. It really talked about that there needs to be more than a 50/50
08:34:59 evaluation of the evidence for it to go to the jury.

And our thought was that when it comes to something like future medical expenses, which is the topic of paragraph 5, there does have to be some certainty. You just can't tell the jury to make up a number. There has to be
08:35:18 somebody testifying to a number. Whereas the last paragraph on the first page of page 18 is not talking about expenses. It's talking about pain and suffering, which really can't be subjected to any sort of a certain number. Rather, it seems to us it's a preponderance of the evidence that needs to be
08:35:37 shown there's likely to be pain and suffering.

So that's why we ended up going with the language the plaintiff proposed at the bottom of the first page on instruction 18.

And then the other change we made was to the verdict
08:35:56 form, which I think you have received. Reordering the numbers of the claims and then putting an instruction in a parenthetical before the two design defect claims.

Are there any comments or thoughts? Your objections on this stuff is preserved. But are there any comments or
08:36:20 thoughts on what we have in hand this morning?

08:36:22 MR. CLARK: Your Honor, for the plaintiff -- and, by the way, we do apologize for Traci's effort, and your staff has been very accommodating. We will not make this an issue next time.

08:36:32 But with respect to the -- I don't have any problems with the proposed jury instructions. I do have some concern with an asterisk on it because --

THE COURT: With what?

MR. CLARK: I'm sorry. On the liability instruction

08:36:46 number 1. You've added language to the strict liability design verdict form --

THE COURT: Where are you?

MR. CLARK: I'm sorry. The verdict form, Your Honor.

THE COURT: Ah. Okay.

08:36:58 MR. CLARK: I apologize.

Number 1, you've added the parenthetical "You may not find Bard liable on this claim unless you also find that Bard" -- and there's a little typo there, it should be "is liable" if we're going to keep this language, "on the

08:37:12 negligent design claim."

I agree that the jury could not find Bard negligent without first finding them strictly liable. I don't think it's accurate that they could not find them negligent -- I'm sorry, could not find them strictly liable without finding

08:37:28 them negligent. I think they're similar. I just -- I'm not

sure that they're coextensive that way. I think there is kind of a one-way rachet there. So I just don't know that that first parenthetical is a correct statement of the law.

And I apologize, I just looked at this five minutes ago so I haven't had a chance to do any research to see if there is a scenario where there could be strict liability under Georgia law without there being negligence. And I guess I just posed that question while I'm frantically trying to think if there's a problem with it.

THE COURT: I guess I'm confused. I thought yesterday we agreed that we need to put that instruction in both the strict liability and the negligent design claim. In other words, you can't decide one without the other.

MR. CLARK: I thought the reason for having it in both to was make sure the jury understood that they're linked in the sense that the jury could not find that the design was negligent without also finding that it was strict liability because of the risk/benefit analysis.

I don't know that it is the case that they could not find Bard strictly liable without also finding them negligent.

I think that -- it's almost like strict liability is sort of a lesser-included offense for the negligent claim. But I think the jury could potentially find Bard strictly liable without also finding it negligent.

The reverse is not true. But I do think it could go

08:38:52 the other way.

THE COURT: I think what I hear you saying, Mr. Clark, is that the jury could look at the design, decide that under the risk utility analysis it was defective, but
08:39:20 also conclude that Bard did everything it could so it wasn't negligent. But it's nonetheless defective and therefore Bard is strictly liable.

MR. CLARK: That's a better way of putting it. I was thinking more in terms of a jury could say, yes, this is a
08:39:38 defective and unreasonably dangerous product and therefore Bard is strictly liable because the risks don't outweigh the benefits -- or the risks outweigh the benefits. However, Bard was reasonable. Or something like that. Or we're not going to find that they're negligent, but it could be strictly
08:39:49 liable.

THE COURT: That's a more complicated idea to explain than just putting this instruction into the negligence instruction; right?

MR. CLARK: I don't know that we'd have to explain it
08:40:03 other than instructing them that they would have to find strict liability as a condition of finding negligent design, but we don't have to tell them that they would have to find negligence as a condition of finding strict liability. Right now they're connected both ways and it should only be
08:40:16 connected one way.

08:40:18 THE COURT: All right.

What are the defendants' thoughts?

MR. NORTH: Your Honor, I believe, based on the cases that we discussed last Friday and the jury instructions, that
08:40:27 the two causes of action are coextensive. The risk/benefit factors that apply the strict liability also apply the negligence claim. That's been made very clear by the Georgia courts. Even the pattern charge on strict liability says you must decide whether the manufacturer acted reasonably. The
08:40:47 same principles of reasonableness underlie both claims. So I think they're coextensive each way.

THE COURT: It's this Georgia law again. I mean, there's no doubt that the cases do say that they're injecting a reasonableness requirement into strict liability. Which was
08:41:14 why I said last week therefore it's not strict liability. And it's why some of the lower Georgia courts have said there are not two claims anymore, there's only one.

Given that fact, Mr. Clark, what are your thoughts? I mean, I agree doctrinally, if we were talking about true
08:41:35 strict liability, you're right, you don't have to find negligence. But it is true that the Georgia courts have said the risk/benefit analysis injects a reasonableness requirement into the strict liability claim. And, of course, that's the essence of a negligence claim, is somebody acted unreasonably.

08:41:55 MR. CLARK: My concern is it's essentially kind of

creating a double burden on the plaintiff and kind of have to prove both things to get one of the two.

THE COURT: Well, you're right, but don't you think that's what the Georgia case law says? I mean, Georgia case law says for strict liability you have to apply the risk/benefit analysis and you have to apply a reasonableness requirement. So it does give you both burdens.

MR. CLARK: It does inject reasonableness. The cases do say that.

THE COURT: Could you all get this clarified before our next Georgia bellwether trial?

MR. NORTH: No, but I can give you the names of a couple of the Georgia Supreme Court justices. It may help.

THE COURT: That's why I mentioned Dave Nahmias. And when I told him about it, all he did was shake his head and close his eyes. So I think he's aware of it.

Do you have thoughts, Jeff?

MR. KILMARK: I agree negligence is part of the strict liability. I know the case last week had applied that standard to both causes of action.

THE COURT: Jeff mentions again there was -- on May 24th last week there was a Georgia Court of Appeals decision that again said risk utility and reasonableness are part of strict product design defect.

MR. CLARK: We agree with that. It's the second part

of it.

THE COURT: Well, I guess the question I would ask is this, Mr. Clark: Given that state of Georgia law, how would you suggest we change the instructions if we're going to be true to Georgia law?

MR. CLARK: Your Honor, I'd like to confer with my colleagues, but there's a big part of me that says maybe we basically merge 14 and 15 into one instruction or just call it defective design and abandon this sort of what appears to be a increasingly thin distinction between strict liability and negligence. And that way maybe we don't that have.

I have some concern that the jury may take a negative connotation that we have a claim that we presented and told the jury we were presenting and now they're not seeing it. But we need to, I guess, weigh that risk.

THE COURT: Okay. Before we do that, let's see what else we've got on jury instructions or verdict form.

Anything else?

MR. CLARK: Well, you had proposed some language with respect to the FDA.

THE COURT: Oh. Thank you. Yes. I jumped right over that. Yes. That is instruction 7, I think.

Yeah, I tried to be true to what's in the regulation. That's why 2(b) is so wordy. But also to simplify it somewhat for the jury's understanding.

08:44:41 So what are your thoughts on the language?

MR. CLARK: Your Honor, I think you did a good job. We would agree to this charge. I think it's an accurate statement of the law and I think it's important that the jury
08:44:50 understand that. And this puts it all in one place where it's not necessarily conspicuous or a comment on the evidence.

THE COURT: What do the defendants think?

MR. NORTH: Your Honor, I think it is an accurate statement of the law.

08:45:01 THE COURT: Okay.

Anything else on the instructions or verdict form?

MR. NORTH: Your Honor, only for the reasons we stated yesterday, we believe that if you're going to link the two design claims you should also link the two warning claims
08:45:14 in the verdict form and the instructions. But we understand the Court does not agree.

THE COURT: Okay.

Let me ask one other question before I give you five minutes to confer. And it just has to do with my having
08:45:26 thought about our 1000 -- Rule 1006 exhibit.

Do defendants intend to argue anything about that exhibit in closing?

MR. NORTH: Yes, Your Honor.

THE COURT: Tell me, in essence, what you're going to
08:45:38 argue. There's a circuit split on how Rule 1006 exhibits

should be received, and there's some courts that call for an instruction. I just want to make sure that I'm acting appropriately in not instructing.

What --

MR. NORTH: Your Honor, what we intended to do is where they total up the number of complaints in various failure modes, we believe a lot of their totals that they have come up with disprove some aspects of their claim, and we intend to look at those totals with the jury. We do not intend to go through the narrative descriptions.

THE COURT: Well, I take it, then, what you're going to do is argue, in effect, that these totals are correct, they help us.

MR. NORTH: Yes, exactly.

THE COURT: You're not going to argue these totals are unreliable, you shouldn't consider them --

MR. NORTH: No, no.

THE COURT: Okay. I think that solves the issue.

The split in the circuits is there are some circuits that say a Rule 1006 summary is not evidence and the jury should be instructed it's not evidence and they should consider the underlying evidence, and that could lead a party to argue, well, they didn't present the underlying evidence so you can disregard it.

The Ninth Circuit has not followed that line of

08:46:55 cases. And I think that line of cases is contrary to Federal Rules of Evidence 1006. But the Ninth Circuit hasn't said much, but there's a 1995 decision that says a 1006 summary is evidence. Obviously it's been admitted that way, so I don't
08:47:10 think I need to give any instruction.

And since you're not going to be arguing it's unreliable, I think we're okay on that point.

Okay. Why don't you take a minute to talk about that and we'll just wait while you do.

08:47:21 (Counsel confer.)

MR. CLARK: After conferring, what the plaintiff would propose is to eliminate instruction 15 and add the word "negligent" -- words "negligent and" before "strictly liable."

In other words, the first sentence of instruction 14
08:49:40 would say "Mrs. Jones contends that Bard is negligent and strictly liable," and then we can eliminate the information that you've added that's underlined in my copy.

THE COURT: So you'd leave instruction 14 the way it is, just clarifying in the first sentence that she contends
08:50:02 Bard is negligent and strictly liable, and take out the underlined language?

MR. CLARK: I would take out the "This instruction will govern" sentence or two.

THE COURT: All right.

08:50:18 You'd take out instruction 15 and the separate

negligence claim in the verdict form?

MR. CLARK: Yes. What we would do for the verdict form would be to omit the word "strict" from number 1 to say "Product Liability Design Defect Claim."

And then take out the word "strict" again in the secondary instruction.

And then I would take out design defect claim number 2 on page 2.

THE COURT: Mr. North, what do you think?

MR. NORTH: Your Honor, I have no objection to the change they propose to the instruction. I'm not sure I caught what they're saying about the verdict form. Did they say to omit the word "strict product liability"?

THE COURT: No. Just omit "strict." So it would be "Product Liability Design Defect Claim."

MR. NORTH: And then would that include eliminating number 2 altogether?

THE COURT: Yes.

MR. NORTH: Okay. No objection to that, Your Honor.

THE COURT: Okay. Let's just make sure, then, that I'm getting this right since I'm going to be instructing the jury shortly.

So on instruction 14 -- well, actually, we need to go back to instruction 12.

MR. CLARK: I think we can cure that by just

08:51:44 eliminating the word "strict" and striking number 2.

THE COURT: So in instruction 12 we'll say "Ms. Jones asserts three claims"?

MR. CLARK: Yes.

08:51:55 THE COURT: "Against Bard. One, Product Liability Based on Design Defect.

"Two, Strict Product Liability Based on Failure to Warn."

"And, three, Negligent Failure to Warn."

08:52:14 And then presumably we would restore the last sentence which says, "You should consider each claim separately."

MR. CLARK: Yes, Your Honor.

THE COURT: Is that agreeable, Mr. North?

08:52:24 MR. NORTH: Yes, Your Honor.

THE COURT: And then on instruction 14 -- my pages have gotten mixed up and we don't have page numbers on here.

I think I've got it sorted out.

So on 14 we would say -- how about if we say in the

08:52:59 first sentence, rather than "negligent and strictly liable," since we've taken "strict" out of the other places, just say "Mrs. Jones contends that Bard is liable because of a design defect"?

MR. CLARK: Agreed.

08:53:15 THE COURT: And then I'll take out the underscored

language that refers to instruction 15. And those will be the only changes to instruction 14.

Agreed, Mr. Clark?

MR. CLARK: Agreed.

THE COURT: Mr. North?

MR. NORTH: Agreed.

THE COURT: And then we will delete instruction 15.

We will renumber the rest of the instructions.

On the verdict form 1A -- or A1, I should say, the title will be "Product Liability Design Defect Claim," and we'll take out the parenthetical. And the question will be: "Do you find by a preponderance of the evidence that Bard is liable to Mrs. Jones on the product liability design defect claim?" And we will delete A2 and renumber the next two claims as 2 and 3?

Does that look right, Mr. Clark?

MR. CLARK: Yes, Your Honor.

THE COURT: Mr. North.

MR. NORTH: Yes, Your Honor.

THE COURT: Okay. Let's go ahead and make those changes.

MR. CLARK: Your Honor, would we be permitted to have a copy of the finals before making the closing arguments?

THE COURT: Yeah. We're going to get the changes made, we're going to delete all of the underscoring so you

have a clean copy, and we'll go do that now.

Okay. Anything else we need to address before we get started?

MR. CLARK: I'm sorry. Nothing else -- well, nothing else from the plaintiff.

MR. NORTH: Nothing from the defendant.

THE COURT: Okay. If you want to face the jury, bring the lectern over so it is facing the jury and you can move the mic onto it.

I'll come back when the jury's in.

(Recess was taken from 8:55 to 9:00. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

Good morning, ladies and gentlemen.

JURORS: Good morning.

THE COURT: We are going to start this morning with the jury instructions.

Now that you have heard all of the evidence, it is my duty to instruct you on the law that applies to this case. A copy of these instructions will be sent to the jury room for you to consult during your deliberations.

It is your duty to find the facts from all the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you, whether you agree with it or not. And you must not be

09:02:52 influenced by any personal likes or dislikes, opinions, prejudices, or sympathy.

That means that you must decide the case solely on the evidence before you. You will recall that you took an 09:03:05 oath to do so.

Please do not read into these instructions or anything that I may say or do or have done, as indicating that I have an opinion regarding the evidence or what your verdict should be.

09:03:18 Although there are two defendants in this case, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., you should decide the case as to the two defendants jointly. As a result, in these instructions and in the verdict form, we will refer to the defendants collectively as Bard.

09:03:42 Unless otherwise stated, the instructions apply to both Bard and Mrs. Jones.

The evidence you are to consider in deciding what the facts are consists of the sworn testimony of the witnesses, the exhibits that are admitted into evidence, the facts to 09:04:00 which the lawyers have agreed, and any facts that I have instructed you to accept as proved.

In reaching your verdict you may consider only the testimony of the witnesses, the exhibits received into evidence, and the facts to which the parties have agreed, or 09:04:19 which I have instructed you to accept.

09:04:22 Certain things are not evidence, and you may not consider them in deciding what the facts are. I will list them for you.

First, arguments and statements by lawyers are not 09:04:32 evidence. The lawyers are not witnesses. What they have said in their opening statements, may say in their closing arguments, and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have 09:04:51 stated them, your memory of them controls.

Second, questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the Rules of Evidence. You should not be influenced by the objection or by 09:05:11 my ruling on it.

Third, testimony that is excluded or stricken or that you were instructed to disregard is not evidence and must be not considered. In addition, some evidence is received only for a limited purpose. When I instruct you to consider 09:05:29 certain evidence only for a limited purpose, you must do so and you may not consider that evidence for any other purpose.

Anything you may have seen or heard -- fourth, anything you may have seen or heard when the Court was not in session is not evidence. You are to decide the case solely on 09:05:48 the evidence received during the trial.

09:05:53 Some exhibits admitted into evidence have been partially redacted, which means that certain contents of the exhibit have been blacked out or whited out. The parties and I have redacted information that is not properly admitted as
09:06:08 evidence. You may give the unredacted information in any exhibit whatever weight you choose, but you must disregard the redacted information and must not speculate about what it might say.

You have heard testimony from a number of witnesses
09:06:28 who testified to opinions and the reasons for their opinions. This opinion testimony is allowed because of the education or experience of those witnesses.

Such opinion testimony should be judged like any other testimony. You may accept it or reject it, and you may
09:06:47 give it as much weight as you think it deserves considering the witness's education and experience, the reasons given for the opinion, and all the other evidence in the case.

The FDA's review of a medical device depends on how the device is classified under FDA regulations.

09:07:10 Certain devices are reviewed under the FDA's premarket approval, sometimes referred to as the PMA process, under which the FDA approves a device after finding that it is safe and effective.

Other devices, including the filters at issue in this
09:07:28 case, are reviewed under the FDA's 510(k) process under which

09:07:34 the FDA clears a device after finding that it is substantially equivalent to another device already on the market. The device already on the market is known as the predicate device.

FDA determines whether a device is substantially 09:07:53 equivalent to a predicate device using the following criteria: One, the device has the same intended use as the predicate device; and, two, the device either, A, has the same technological characteristics as the predicate device, or, B, has different technological characteristics but the data 09:08:17 submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data, if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as the predicate device and does not raise different questions of 09:08:38 safety and effectiveness than the predicate device.

Federal law prohibits current FDA employees from testifying in court regarding any function of the FDA, and prohibits current and former FDA employees from testifying about information acquired in the discharge of their official 09:08:59 duties, without authorization of the commissioner of the FDA. As a result, neither side in this case was able to present testimony from current FDA employees or former FDA employees regarding the discharge of their duties related to this case.

Certain charts and summaries not admitted into 09:09:23 evidence have been shown to you in order to help explain the

09:09:27 evidence in this case. These have been referred to as demonstrative exhibits.

A demonstrative exhibit is only as good as the underlying evidence that supports it. You should therefore
09:09:40 give it only -- give the demonstrative exhibits only such weight as you think the underlying evidence deserves.

Certain charts and summaries have been admitted into evidence to illustrate information brought out in the trial. Charts and summaries are only as good as the testimony and
09:10:00 other admitted evidence that supports them. You should, therefore, give these only such weight as you think the underlying evidence deserves.

All parties are equal before the law, and a corporation is entitled to the same fair and conscientious
09:10:20 consideration by you as any party.

Under the law, a corporation is considered to be a person. It can only act through its employees, agents, directors, or officers. Therefore, a corporation is responsible for the acts of its employees, agents, directors,
09:10:41 and officers performed within the scope of their authority.

Mrs. Jones asserts three claims against Bard: One, product liability based on design defect; two, strict product liability based on failure to warn; and, three, negligent failure to warn.

09:11:09 I will instruct you on the law that applies to each

09:11:12 of these claims.

You should consider each claim separately.

Before I give you instructions about Mrs. Jones' specific claims, let me give you a few instructions that will
09:11:25 apply to all of the claims.

When a party has the burden of proving any claim or affirmative defense by a preponderance of the evidence, it means you must be persuaded by the evidence that the claim or affirmative defense is more probably true than not true. You
09:11:46 should base your decision on all of the evidence, regardless of which party presented it.

Some instructions will state that you must find that an event or condition or action was the proximate cause of Mrs. Jones' injury. Proximate cause means that cause which,
09:12:08 in a natural and continuous sequence, produces an event, and without which cause such event would not have occurred. Thus, when I use the expression "proximate cause," I mean a cause that, in the natural or ordinary course of events, produced Mrs. Jones' injury.

09:12:29 In order to be a proximate cause, the act or omission complained of must be such that a person using ordinary care would have foreseen that the event or some similar event might reasonably result.

There may be more than one proximate cause of an
09:12:47 event. Thus, to prove proximate cause, Mrs. Jones need not

09:12:53 prove that an act or omission was the only cause or the last or nearest cause. It is sufficient if it combines with another cause resulting in the injury.

Mrs. Jones contends that Bard is liable because of a 09:13:12 defective design of the Eclipse IVC filter. A manufacturer of a product that is sold as new property may be liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product.

However, a manufacturer of a product is not an 09:13:33 insurer and the fact that a product may cause an injury does not necessarily make the manufacturer liable.

To recover damages for product liability based on a design defect, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

09:13:53 First, the product was defectively designed;

Second, the design defect existed at the time the product left the control of Bard;

And, third, the design defect in the product was a proximate cause of Mrs. Jones' injury.

09:14:15 There is not a single general way to define what constitutes a design defect in a product. Whether or not a product -- whether or not a product is defective is a question of fact to be determined by you, the jury, based on my instructions and the evidence that has been received during 09:14:32 the trial.

09:14:34 Although Bard is not required to ensure that a product design is incapable of producing injury, it has a duty to exercise reasonable care in choosing the design for a product.

09:14:47 To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefit of that product design. You must decide -- must decide whether the manufacturer acted reasonably in choosing a particular product

09:15:09 design by considering all relevant evidence, including the following factors:

The usefulness of the product;

The severity of the danger posed by the design;

The likelihood of that danger;

09:15:27 The avoidability of the danger;

Considering the user's knowledge of the product;

Publicity surrounding the danger;

The effectiveness of warnings and common knowledge or the expectation of the danger;

09:15:40 The user's ability to avoid the danger;

The technology available when the product was manufactured;

The ability to eliminate the danger without impairing the product's usefulness or making it too expensive;

09:15:58 The feasibility of spreading any increased cost

09:16:02 through the product's price;

The appearance and aesthetic attractiveness of the product;

The product's utility for multiple uses;

09:16:12 The convenience and durability of the product;

Alternative designs of the product available to the manufacturer;

And the manufacturer's compliance with industry standards or government regulations.

09:16:29 In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Mrs. Jones' injury.

In determining the reasonableness of the product

09:16:44 design chosen by Bard, you should consider:

The availability of an alternative design at the time Bard designed the product;

The level of safety from an alternative design compared to the actual design;

09:16:59 The feasibility of an alternative design, considering the market and technology at the time the product was designed;

The economic feasibility of an alternative design;

The effect an alternative design would have on the

09:17:16 product's appearance and utility for multiple purposes;

09:17:19 And any adverse effects on Bard or the product from using an alternative design.

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal 09:17:33 or state safety and nonsafety standards or regulations and industry-wide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the 09:17:54 manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

In deciding whether the design of the Eclipse filter was defective you may also consider whether the FDA instituted 09:18:13 regulatory action with respect to the Eclipse filter. However, a product may be defective even if the FDA institutes no regulatory action.

If you decide that the risk of harm in the product's design outweighs the utility of that particular design, then 09:18:30 the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design, and the product is defective.

If, after balancing the risks and utilities of product you find by a preponderance of the evidence that the 09:18:50 product suffered from a design defect that proximately caused

09:18:54 Mrs. Jones' injury, then Mrs. Jones is entitled to recover.

Mrs. Jones contends that Bard is strictly liable because it failed to give adequate warnings regarding the Eclipse IVC filter.

09:19:18 The manufacturer of a product that is sold as new property may be liable to any person who is injured because of an inadequate warning with respect to the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer and the fact that

09:19:38 a product may cause an injury does not necessarily make the manufacturer liable.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but, instead, has a duty to warn the patient's

09:19:57 doctor, who acts as a learned intermediary between the patient and the manufacturer.

To recover damages for strict liability based on inadequate warning, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

09:20:15 First, the warning given with the product was inadequate;

Second, the inadequate warning existed at the time the product left the control of Bard;

And, third, the inadequate warning was a proximate

09:20:29 cause of Mrs. Jones' injury.

09:20:32 There is no single way to define what constitutes an inadequate warning in a product. Whether or not a warning is inadequate is a question of fact to be determined by you, the jury, based on my instructions and the evidence received 09:20:47 during the trial.

Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its Eclipse IVC filter. Bard owes this duty to warn to all physicians whom the manufacturer should reasonably foresee may 09:21:07 use the product. Bard's duty to warn may have been breached by failing to provide an adequate warning of the Eclipse filter's potential dangers or failing to adequately communicate to Mrs. Jones' physicians the warning provided.

A manufacturer's duty to warn arises when the 09:21:29 manufacturer knows or reasonably should know of the danger presented by the use of the product.

A manufacturer has a continuing duty to adequately warn of defects in a product even after that product has left the control of the manufacturer.

09:21:50 You must decide whether adequate efforts were made by Bard to communicate all risks that were known or reasonably should have been known to Bard to the physician who implanted the Eclipse filter in Mrs. Jones and whether the warning that Bard communicated was adequate.

09:22:07 A product, however well or carefully made, that is

09:22:12 sold without an adequate warning of such danger may be said to be in a defective condition.

If you find by a preponderance of the evidence that Bard did not adequately warn when an adequate warning should 09:22:26 have been given, and that this inadequate warning proximately caused Mrs. Jones' injury, then you may find the Eclipse filter to be defective and for that reason find that Mrs. Jones is entitled to recover.

Mrs. Jones claims that Bard was negligent in failing 09:22:48 to warn about the risks of the Eclipse IVC filter Dr. Avino implanted in her. To recover on this claim Mrs. Jones must prove by a preponderance of the evidence that:

One, Bard had a duty of reasonable care to warn about the risks of the Eclipse IVC filter;

09:23:08 Two, Bard breached that duty in the adequacy of the warnings about the Eclipse filter provided to Dr. Avino;

Three, the breach was a proximate cause of Mrs. Jones' injury;

And, four, she suffered damages.

09:23:26 Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved in the 09:23:41 product, but instead has a duty to warn the patient's doctor,

09:23:46 who acts as a learned intermediary between the patient and the manufacturer.

The parties agree that Bard had a duty of reasonable care to warn about risks of the Eclipse IVC filter. If 09:23:58 Mrs. Jones has failed to prove any of the other elements -- any other element by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the risks of the Eclipse filter she received.

It is my duty to instruct you on the measure of 09:24:21 damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Jones on any or all of her claims, you must determine her damages. Mrs. Jones has the burden of proving damages by a preponderance of the evidence. 09:24:42 It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on speculation, guesswork, or conjecture.

Damages are given as pay or compensation for injury done. When one party is required to pay damages to another, 09:25:05 the law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence that Mrs. Jones is entitled to recover damages, you should award to Mrs. Jones such sums as you believe are reasonable and just in this case.

09:25:25 Necessary expenses resulting from the injury are a

09:25:29 legitimate item of damages. As to medical expenses, such as hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expenses as were reasonably necessary.

09:25:46 Mrs. Jones seeks to recover not only for her past medical expenses, but also for medical expenses that may be incurred in the future. If you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses for removal of the Eclipse filter fragment

09:26:08 and that the expenses were proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such future medical expenses, Mrs. Jones would be entitled to recover those amounts reduced to present cash value.

09:26:28 Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. Questions of whether, how much, and how long Mrs. Jones has suffered or will suffer are for you to decide.

09:26:50 Mrs. Jones seeks to recover for past physical pain and suffering for her hospitalization in April 2015. She is not making any further claim for physical pain and suffering unless she has another procedure related to the filter. If you find that the evidence shows that it is more likely than

09:27:09 not that Mrs. Jones will incur future pain and suffering, she

09:27:13 would be entitled to recover an amount based on the enlightened conscience of fair and impartial jurors.

Pain and suffering includes mental suffering, but mental suffering is not recoverable as damages unless there is 09:27:30 also physical suffering. In evaluating Mrs. Jones' pain and suffering, you may consider the following factors if proven:

Interference with normal living;

Interference with enjoyment of life;

Impairment of bodily health and vigor;

09:27:48 Fear of extent of injury;

Shock of impact;

Actual pain and suffering, past and future;

Mental anguish, past and future;

And the extent to which Mrs. Jones must limit 09:28:03 activities.

If you find that Mrs. Jones' pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Mrs. Jones will endure. In making such an award your standard should be your 09:28:20 enlightened conscience as impartial jurors. You may take into consideration the fact that Mrs. Jones is receiving a present cash value award for damages not yet suffered.

Bard must take Mrs. Jones in whatever condition it finds her. A negligent actor must bear the risk that its 09:28:43 liability will be increased by reason of the actual physical

09:28:47 condition of the person toward whom the act is negligent. Thus, if you find that Mrs. Jones' injuries were increased by her existing physical condition, you may award damages for those increased injuries provided you find they were
09:29:03 proximately caused by Bard.

No plaintiff, however, may recover for injuries that are not proximately caused by the defendant.

When a person is injured by the negligence of another, she must mitigate her damages as much as is
09:29:24 practicable by the use of ordinary care and diligence.

If you find that Mrs. Jones has suffered damages as alleged, under the law she is bound to reduce those damages as much as is practicable by the use of ordinary care. If you believe that by the use of such care she could have reduced
09:29:45 the damages, you would determine to what extent and reduce such damages to that extent.

In cases such as this, there may be aggravated circumstances that warrant the award of additional damages called punitive damages. Punitive damages are intended to
09:30:11 punish, penalize, and deter wrongful conduct.

Before you may award punitive damages, Mrs. Jones must prove that the actions of Bard showed willful misconduct, fraud, wantonness, oppression, or that entire want of care that would raise the presumption of conscious indifference to
09:30:34 consequences.

09:30:35 Mrs. Jones must make this proof by clear and convincing evidence. This is a different and higher burden of proof than a preponderance of the evidence, but is less than the standard of beyond a reasonable doubt that is required in 09:30:51 criminal cases.

Clear and convincing evidence is defined as evidence that will cause you to firmly believe, to a high degree of probability, that the requirements for punitive damages have been proved.

09:31:05 If Mrs. Jones fails to prove by clear and convincing evidence that Bard was guilty of willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that would raise the presumption of conscious indifference to consequences, then you may not award punitive damages. Mere 09:31:28 negligence, even amounting to gross negligence, will not alone authorize an award of punitive damages.

In the verdict form you will be asked to specify whether Mrs. Jones is entitled to recover punitive damages, but you will not yet be asked to determine an amount of 09:31:48 punitive damages. If you decide that she should be awarded punitive damages, then you will receive some brief additional instructions, evidence, and argument before setting the amount.

There can be no recovery of punitive damages in this 09:32:07 case unless there is first a recovery by Mrs. Jones of

09:32:11 compensatory damages.

Before you begin your deliberations, please elect one member of the jury as your presiding juror. That presiding juror will preside over the deliberations and serve as the 09:32:27 spokesperson for the jury in court.

You shall diligently strive to reach agreement with all of the other jurors if you can do so. Your verdict, whether for the plaintiff or for the defendant, must be unanimous.

09:32:42 Each of you must decide the case for yourself, but you should do so only after you have considered all of the evidence, discussed it fully with the other jurors, and listened to their views.

It is important that you attempt to reach a unanimous 09:32:58 verdict. But, of course, only if each of you can do so after having made your own conscientious decision. Do not be unwilling to change your position, your opinion, if the discussion persuades you that you should. But do not come to a decision simply because other jurors think it is right or 09:33:18 change an honest belief about the weight and the effect of the evidence simply to reach a verdict.

Because you must base your verdict only on the evidence received in the case and on these instructions, I remind you again that you must not be exposed to any other 09:33:36 information about the case or to the issues it involves.

09:33:41 Therefore, except for discussing the case with your fellow jurors during your deliberations, do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it. This includes discussing the case in person, in writing, by phone or electronic means, via e-mail, text messaging, or any internet chat room, blog, website, or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, SnapChat, or any other forms of social media.

We didn't have to give that instruction five years ago.

This applies to communicating with your family members, your employer, the media or press, and the people involved in the trial.

If you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter, and to report the contact to the Court.

Do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it. Although I don't have reason to think there are such accounts, but be sure to avoid them.

Do not do any research, such as consulting dictionaries, searching the internet, or using other reference

09:35:06 materials, and do not make any investigation or in any other way try to learn about the case on your own.

Do not visit or view any place discussed in this case, and do not use internet programs or other devices to 09:35:20 search for or view any place discussed during the trial.

Also, do not do any research about this case. The law, the people involved, including the parties, witnesses, or lawyers, until you have been excused as jurors. If you happen to read or hear anything touching on this case in the media, 09:35:39 please turn away and report it to me as soon as possible.

As I have explained before, these rules protect each party's right to have this case decided only on evidence that has been presented here in court. Witnesses in court take an oath to tell the truth, and the accuracy of their testimony is 09:35:59 tested through the trial process.

If you do any research or investigation outside the courtroom or gain any information through improper communications, then your verdict may be influenced by inaccurate, incomplete, or misleading information that has not 09:36:17 been tested by the trial process.

Each of the parties is intended -- is entitled to a fair and impartial jury, and if you decide the case based on information presented in court, you will have denied the parties a fair trial. Remember that you have taken an oath to 09:36:36 follow these rules, and it is very important that you do so.

09:36:42 A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start over.

If any of you is exposed to any outside information, 09:36:54 please notify me immediately.

The exhibits received in evidence that are capable of being displayed electronically will be provided to you in that form, and you will be able to view them in the jury room. A computer, a projector, a printer, and accessory equipment will 09:37:13 be available for you in the jury room.

A court technician will show you how to operate the commuter and other equipment, how to locate and view the exhibits on the computer, and how to print the exhibits.

You will also be provided with a paper list of all 09:37:30 exhibits received in evidence. And there may be some paper copies of exhibits, I'm not sure about that. We're working on that issue.

You may request a paper copy of any exhibit received in evidence by sending a note through the bailiff.

09:37:44 If you need additional equipment or supplies or if you have questions about how to operate the computer or other equipment, you may send a note to the bailiff, signed by your presiding juror, or by one or more members of the jury. Do not refer to or discuss any exhibit you are attempting to view 09:38:03 if you send a note out.

09:38:05 If a technical problem or question arises and requires hands-on maintenance or instruction, a court technician may enter the jury room with the bailiff present for the sole purpose of assuring that the only matter that is
09:38:20 discussed is the technical problem.

When the court technician or any nonjuror is in the jury room, you should not deliberate. No juror should say anything to the court technician or any other nonjuror, other than to describe the technical problem or to seek information
09:38:37 about the operation of the equipment. Do not discuss any exhibit or any aspect of the case while these individuals are in the jury room.

The sole purpose of providing the computer in the jury room is to enable you to view the exhibits received in
09:38:53 evidence in the case more easily. You may not use the computer for any other purpose. At my direction, technicians have taken steps to ensure that the computer does not permit access to the internet or to any outside website, database, directory, game, or other material. Do not attempt to alter
09:39:15 the computer or obtain access to such materials.

If you discover that the computer provides or allows access to such materials, you must inform me immediately and refrain from viewing those materials.

Do not remove the computer or any electronic data
09:39:34 from the jury room, and do not copy any such data.

09:39:40 If it becomes necessary during your deliberations to communicate with me, you may send a note through the bailiff. And we will be swearing Nancy and Traci as bailiffs, so they'll be the ones who can work with you. The note should be
09:39:53 signed by any one or more of you using your juror number rather than your name.

No member of the jury should ever attempt to communicate with me except in a signed writing. I will not communicate with any of you on anything concerning the case
09:40:07 except in writing or here in open court with the parties present.

If you send out a question, I will consult with the parties before answering it, which may take some time. You may continue your deliberations while waiting for the answer
09:40:23 to any question.

Please remember that you are not to tell anyone, including me, how the jury stands, whether in terms of vote count or otherwise, until after you have reached a unanimous verdict or have been discharged. Do not disclose any vote
09:40:41 count in any note you send to me.

A verdict form has been prepared for you. We think it is self-explanatory. It has a section titled "Liability," where you just indicate yes or no, whether you believe Mrs. Jones has proven any of the three claims she's listed.

09:41:00 There is then a section for compensatory damages if

09:41:04 you decide to award them. And then a question where you indicate whether or not you find that punitive damages are warranted.

After you have reached a unanimous verdict, your 09:41:16 foreperson should complete the verdict form according to your deliberations, sign and date it using your juror number rather than your name, and advise the bailiff that you are ready to return to the courtroom.

Counsel, are there any additions or corrections to 09:41:32 the instructions?

MR. STOLLER: None from plaintiff, Your Honor.

MR. NORTH: Nothing for the defendant, Your Honor.

THE COURT: All right.

We are going to proceed with the plaintiff's closing 09:41:44 argument. We'll then take the morning break after the plaintiff's closing argument and before the defendants' closing argument.

I think we'll be done by noon. If we run a few minutes over, we'll keep going so that we finish the argument 09:41:57 before we break for lunch so that you can start deliberating during the lunch hour.

All right. Plaintiff's counsel.

Before we start, Tricia has asked that we all stand for a minute. Good point. Everybody can stand up.

09:42:12 Go ahead, Mr. O'Connor.

09:43:31 MR. O'CONNOR: Thank you, Your Honor. May it please the Court, members of the jury, good morning.

Last night as I thought about talking with you today and I was thinking about where I would start, and I started 09:43:55 thinking about the very first witness who came in to talk to you.

I really thought about where this case all started. Started back in about 1999, 2000, and it started with Dr. Murray Asch. And I thought about Dr. Asch last night and 09:44:15 I thought about how excited he must have been, how thrilled as a doctor, an interventional radiologist, to be part of something new, something that would help patients. Something that he believed had a chance at being good for medicine, the retrievable filter. The Recovery.

09:44:41 I thought about Dr. Asch and how flattered and proud he must have been when Bard, the big medical device company, sought him out and chose him, an interventional radiologist in Canada, to run the pilot study for retrievability of the Recovery filter.

09:45:05 And how conscientious he was. How he went to his hospital's ethics committee and how he went to Health Canada and how he set up the whole program and worked hand in hand with Bard and NMT. He wanted this to work and he was thrilled to be a part of it. And he was -- knew that his study would 09:45:30 be important some day because it would help determine whether

09:45:35 a filter known in the medical community to be permanent could actually be retrieved.

And during that study, I thought about Dr. Asch and -- and when he was looking at the imaging that one morning 09:45:54 he told us about. And he came across Patient 9 and he saw the imaging, the radiograph, and he saw that filter that migrated upward, cephalad migration, and how concerned he became. How concerned he became about a patient who was under the care of another doctor, who was asymptomatic but who had a Bard 09:46:23 Recovery filter that didn't act as -- the way it was supposed to act.

And how he immediately got on the phone with Patient 9's doctor and talked to him and wanted to make sure everything was going to be okay.

09:46:43 And it's a good thing that this was found in Dr. Asch's study because, after all, these patients were monitored. Patient 9 was lucky because Dr. Asch happened to coincidentally see that moved filter, the Recovery filter, and got on the phone with Patient 9's doctor.

09:47:09 And even then, Dr. Asch remained optimistic. And why not. He told Bard that the Recovery wasn't ready for market. But Bard assured him that there was going to be a long-term study, something Dr. Asch knew was necessary. And Bard told him, they told him not to worry because if this happened again 09:47:43 in the study, they would suspend the study.

09:47:48 Imagine how Dr. Asch felt. Because of him, Patient 9's filter was discovered, and he had a company, Bard, who gave him assurances. And that must have felt good to have that type of a trusting relationship with a big company that
09:48:11 chose him, Dr. Murray Asch.

And, importantly, Bard assured Dr. Asch that not only was it going to do a long-term study, but that it would never use his study, a short-term clinical study, for retrievability to establish clearance with the FDA, to establish substantial
09:48:40 equivalence.

Well, as we know the story and how it goes, Dr. Asch went on his way professionally. And he never heard from Bard again. But he was optimistic. Things were different in Canada.

09:48:58 And then he heard on the streets, not from Bard, but on the streets, from other doctors who were learning that this Recovery filter was migrating and breaking and hurting and causing serious health consequences to patients.

And you saw Dr. Asch, and he wondered why wouldn't
09:49:20 this company I had this relationship have called me to tell me that?

And he called Bard. And he said, hey, I heard about what's going on with the Recovery filter. I want to get every one of my patients back in. Will you help me find them?

09:49:39 And they said no. They said no.

09:49:44 And Dr. Asch went on to find out that there wasn't a long-term study.

And it was here in this courtroom for the first time where Dr. Asch learned that contrary to his belief, contrary 09:50:02 to his trust, Bard went ahead and used his study, used his good name to get clearance for the permanent Recovery filter. Dr. Asch felt betrayed.

And -- and that's where it all started. Because what the evidence showed, when you think about why would this 09:50:46 happen, why wouldn't Bard contact the very doctor that they obviously relied upon to help them find if this filter could really be retrievable, really break into this market. Bard wanted this market and they wanted it bad. They saw an opportunity. A big opportunity. They knew that the race to 09:51:09 the market had to be won by them because the winner of the race to the market would get the market share.

And so what happened to this system? Well, I think the evidence has shown us that what Bard Peripheral Vascular is, it's got two sides to the company. It's got the science 09:51:33 side, the engineering side, the testing side. The science side. But it also has the corporate side, the marketing people, the people who write up those monthly reports who keep track of sales. Corporate. The suits.

And what happened was, and we saw, aggressive 09:51:58 marketing became the philosophy of Bard. And, sure enough,

09:52:06 the suits won over science. And it continued from the Recovery to the G2, to the G2X, to the Eclipse, and it continues today.

And think about the Eclipse. And think about 09:52:22 aggressive marketing and think about how the suits won over science.

What did we learn? The Eclipse is the G2X with electropolishing. Bard knew the technology to stop the problem the G2 was experiencing no longer was it going up that 09:52:47 much, it was going down, caudal migration, and what they learned in the EVEREST study was in the short-term periods of time when patients were heavily monitored, strictly monitored, they were seeing failures.

And in EVEREST they learned that not only were they 09:53:04 seeing failures, but they were seeing migrations and tilts leading to perforations and fractures, and we've called it the cascade, but they knew about it.

And they also knew they to stop it. But Bard couldn't. That would hurt them. That would hurt their bottom 09:53:26 line and it would hurt their reputation. So they gave the Eclipse. And think about what Eclipse means.

And they knew that the Eclipse was only going to be on the market for just that period of time that they needed to get to the next filter. They knew it. They knew its 09:53:45 predicate devices. They knew the history. And they knew how

09:53:48 dangerous it was because it did all the things the G2 did, things that the Recovery did, and they put it on the market. They made that choice.

And they did it knowing they were going to put all
09:54:02 the risk on their patients so they could keep the market share. They did it knowing in January of 2010 that the Eclipse was just there for aggressive marketing to get rid of the baggage, the baggage they wanted to lose. They wanted to lose their history of the Recovery, the G2, the G2X, so call
09:54:26 it the Eclipse. Tell them they're electropolished, and maybe they'll forget about history.

And Doris Jones received the Eclipse. Doris Jones has a strut in her pulmonary artery. Doris Jones is haunted by Bard to this day.

09:54:56 So what this case is, is the race to the market. And how did Bard win it? Aggressive marketing. And what the evidence has shown is that the suits, the suits won. They beat science. Beat science in their own -- own building.

Now, what did we hear from the defense?

09:55:31 We heard a lot of discussion in this case about risk/benefit evidence based upon all retrievable filters. This case isn't about all retrievable filters. This case is about the Eclipse filter and how it got to the market through that predicate system. And it's about the Eclipse and its
09:55:53 defective design.

09:55:54 Now, we brought in experts to talk to you. You heard from Dr. McMeeking, you heard from Dr. Hurst, you heard from Dr. Muehrcke, and you heard, you heard the problem that happens when there's this conical design that will make these
09:56:08 filters susceptible to tilt and migrate, and when that happens it leads to other failures.

But we also had heard evidence in this case that Bard knew how to fix it. Knew it early. And how Bard made a choice. Rather than stop it, stop the harm, stop it, Bard
09:56:37 made a choice and thought it would be cheaper to defend these cases in court and spend money on experts. Not to look at their filters or to figure out how to fix it, but to come in here and fight our experts.

And we showed you, and the evidence showed you, that
09:57:07 there are ways to fix this problem of migration and this cascade of problems. They had the Simon Nitinol filter. Their own medical director talked about what a great filter it was.

But when -- that's what's said when nobody's
09:57:29 watching. The Simon Nitinol filter, why wouldn't doctors be using it? But when people are watching, when they come to a jury, I think you saw what they tried to do with the Simon Nitinol filter.

So the design of the Eclipse and its predicates have
09:57:58 been shown by the evidence as defective and potentially

09:58:01 serious and potentially deadly, and Bard has not brought a single witness in here to defend the design of the Eclipse.

We heard from defendants' experts and we've heard from engineers and we've heard from Bard that filters save 09:58:20 lives. But what Bard did not want to talk about was the Eclipse or its design or what they knew could be done to fix it.

And why is Bard always talking about filters? Because that's where they want to focus this case. Because 09:58:41 they can't talk about the Eclipse. They can't talk about the Eclipse because they don't want to talk about the baggage because the baggage is the reason the Eclipse is here.

And they knew, they knew how bad that design was. And they knew that despite all their statistics, and all their 09:59:05 so-called rates, that there is a whole bunch of people out there who are asymptomatic who may have a fragment in a dangerous location. They may have the silent killer and not know about it.

Now, Judge Campbell has just instructed you, and I 09:59:26 would like to walk through that and talk to you about the instructions.

Let me just go back one.

Doris received her Eclipse filter on August 24, 2010. The Eclipse was cleared for the market in January of 2010.

09:59:55 You've been instructed on the burden of proof. At

09:59:58 the beginning of this trial defense counsel said that they stand wrongfully accused. This isn't a criminal trial, and we all know that. The burden here is by a preponderance of the evidence. And what we, or for them when they have to prove a 10:00:16 defense, have to prove is that facts are probably more true than not true. And we believe that our evidence has established our theories of liability against this company.

So you've received instructions about the elements. Judge Campbell just talked to you about the instructions. And 10:00:48 what I'm going to do is talk to you about the charges and those things that you must deliberate on, and where we see the evidence.

When we talk about a design defect, you see that if the risk of harm in the design of the product outweighs its 10:01:16 utility, the product is defective. And we believe that is what the evidence shows.

And here, the risk of this Eclipse, as the evidence has shown, the one that Doris Jones received, far outweighed any benefits.

10:01:40 And, again, Bard hasn't talked about anything specific about the design-specific benefits of the Eclipse. What they have done is they've tried to stay behind what everybody else is doing, and that is where they want the case to be.

10:01:58 But this case is about the Eclipse and what we have

10:02:02 shown in this evidence, that the way it fails is not a matter of if, it's a matter of when. And Bard knew this. They knew this back in the Asch study, and they knew this in the EVEREST study. Just in those short periods of time they were seeing
10:02:20 failures.

And while, you know, there's no specific way as to defining what constitutes a design defect, you, the members of the jury, you will decide based upon the evidence, and should decide, whether in choosing this design Bard acted reasonably.
10:02:46 And there's a number of factors that you've been instructed about.

First, one of the factors is the usefulness of the design. And what we think that the evidence has shown, the overwhelming evidence, is that there's no evidence that this
10:03:14 device saves lives. And certainly there's no evidence that this device saved Doris Jones' life. She doesn't have a filter, she has a piece. A piece that causes her anguish every moment of every day.

You heard from Janet Hudnall. She was the architect
10:03:38 of the marketing of the Recovery and the first retrievable. And you heard her testimony. She even admitted then in deposition, right here in this court, that there's no way to know if a filter has stopped a clot. And there really isn't.

And then, if you recall, Dr. Frederick Rogers, who
10:04:02 conducted the clinical research for 20 years. He looked at

10:04:10 patients, the trauma patients. And if you remember his testimony, he was surprised by the results of that study. What he testified to is we do not know, based upon this study, whether or not the vena cava filters were effective in 10:04:30 decreasing the rate of fatal PE, which is important.

Remember, you saw him on videotape. And he was a former colleague of Dr. Morris'.

And another factor is the severity of danger posed by the design.

10:04:59 If you remember what Dr. Muehrcke said, this was all new to the medical community. They had never seen these types of problems. Bard filters were fracturing and going into places where difficult choices had to be made.

And if you remember the testimony from Doris' doctor, 10:05:22 where that filter strut landed in her pulmonary artery, it was just too dangerous to remove. Understandably, not every doctor who doesn't see these every day may not have the skill set. But that's what this filter has caused. The risk/benefit decisions that doctors make now aren't whether to 10:05:43 use these filters, it's whether to take these pieces out to free these patients of Bard.

You heard from Dr. Moritz yesterday, Mark Moritz, the very last witness that you heard from, you heard from him on videotape. He's from New Jersey. He's a cardiovascular 10:06:05 surgeon. He's not our expert.

10:06:07 And he said he is concerned about Doris. He doesn't even know her. But what he said is that this strut in her pulmonary artery, it can change at any moment.

If you remember, he went through the literature, 10:06:33 we've heard a lot of testimony about that, and all the literature that he had reviewed concerned Bard filters, and it all confirms that Bard filters were the worst in terms of failures and complications.

Dr. Moritz knew that Doris received this filter and 10:06:55 it was intended to be permanent. And what that meant to the medical community, and that's how Bard was promoting them, is that when that filter goes in, it should stay in the same place for the duration of a patient's life.

And Dr. Moritz testified that Doris' doctors and 10:07:19 Doris could not have reasonably expected for this to happen to her. Who would? Bard promoted this filter and promoted electropolishing.

Bard didn't tell the medical community that all it was was the G2 and the G2X that had a history of problems that 10:07:41 the medical community knew was bad.

And Dr. Moritz talked about having that strut. And while the defense wants to talk about asymptomatic, that's pretty easy. It's defense. That's a way of keeping your distance from this, say it's asymptomatic and hope you can 10:08:07 come here to court and use the asymptomatic defense. No harm,

10:08:12 no foul.

But what we do know is that foreign objects in patients' bodies are dangerous. What we do know is that there are diseases out there that are asymptomatic that kill people.

10:08:25 And what Dr. Moritz told us was that by having this strut in the pulmonary artery, it exposes Doris to bleeding, to erosion of the artery, to infection, and to vascular thrombosis.

We'll talk more about Doris, but that's what she

10:08:56 deals with every single day, every moment, is that.

There it is.

And you'll recall Dr. Hurst talked about this. And you can see where the strut is. We've highlighted it in yellow, too, and with the arrow. It haunts her every day.

10:09:34 Every day. And the way Bard distanced itself away from patients like her is they tout that it is asymptomatic. But we know, we know what Bard knows. And Bard knows that fractures are serious and that fractures that embolize are silent, deadly, and harmful. They knew that, and they knew

10:10:04 that as early as Dr. Asch's study in 2000, because they saw a doctor who was compassionate, a doctor who was conscientious, and a doctor who saw a filter migrate in a patient who had no symptoms. And even back then Dr. Asch stressed how serious that is.

10:10:42 Likelihood of danger. We found that in the

10:10:44 Murray Asch study. And then you saw testimony from the sales representative, Jason Greer, and the e-mail he sent to Janet Hudnall about that way they were able to keep the Recovery on the market and move on. Keeping it together with
10:11:05 Scotch tape, tears, and mirrors.

There was no testing by Bard which considered the vena cava dynamics. That's a fact. And if you look at Exhibit 45, you'll see. And note that, because Bard lamented that they -- in an e-mail, "I must strongly caution against
10:11:32 emphasizing Recovery's ability to center in the cava to the point where it's the focus of the product's positioning." "Stability" was the word they were using. "We knew very little about the long-term clinical performance of the device." Of course they didn't know anything about it because
10:11:50 they broke their promise to Dr. Asch. And then after a year of commercialization, they still had so many questions that had to be answered.

And again, likelihood of danger. Dr. Moni Stein, Bard's expert who came in here, he talked about the medical
10:12:11 literature on Bard filters, and he quoted that at five years there's a fracture prevalence was estimated to be 38 percent in G2 filters. That's a study he read.

We know now, and Bard knew then, that the G2 wasn't any better than the Recovery, because in another study, a
10:12:32 study for retrievability of the G2, they saw failures and

10:12:39 complications. And not only that, Bard began to see that not only was tilting and migrating bad, but it led to others, perforation and fracture.

We've assembled the complaint chart for your review, 10:13:04 it's Exhibit 4565. Ten sample complaints from each of the filters. Take a look at it.

While all medical devices, it can be argued, carry risks, the evidence here has shown that the risk of Bard filters, including the Eclipse, far outweighed any benefit.

10:13:36 And another factor that you should consider is avoidability of danger, the user's knowledge. Recall Dr. Tillman, in which she said -- that was their, Bard's, regulatory expert -- "If it's not performing the way that they expected in the market, they need to do something to address 10:13:54 it."

We talked about Dr. Moritz. He's not our expert. But he agreed that neither Doris' doctors nor Doris should have expected this complication to occur. That just wasn't a reasonable expectation that the medical community had. They 10:14:12 expected these filters to work, stay in place, and not harm the patients.

Same thing in user's knowledge. Don't forget Dr. Anthony Avino, he was the implanting physician. And recall what he testified to. About information that he would 10:14:33 have wanted to know about whether the Recovery filter rates

10:14:41 exceeded rates reported on the MAUDE database.

Bard knew that and they didn't share it. As a matter of fact, to make sure it didn't get out there what Bard knew, they kept it from the sales force. And you know why? Because 10:14:55 sales were important to Bard. And the sales force was important because the sales force developed relationships with doctors and those relationships were built on trust. Doctors looked to the sales force for information. So if the sales force didn't know about the dangers, there was nothing to 10:15:11 report.

And it didn't stop there.

Recall each and every expert from Bard who came in here and testified and was asked the question, "Did you receive, were you provided with Bard's internal documents?" 10:15:29 And how many did you hear say no?

If you provide an expert with what you really have, and show what you've known all along, it's pretty hard to find an honest expert to come in here and testify and go against our experts.

10:15:52 The best way to do it is keep them in the dark the same way they kept doctors and the sales force.

This is 2008. You remember Mike Randall from the Research and Development department. And here again, Bard knew way back in 2008 the relationships due to failures. And 10:16:15 not only that, Bard knew back then that if they eliminated

10:16:19 those failure modes and they knew the technology, they knew how to do it, they knew about caudal anchors, they eliminated those failures, they could reduce the number of complaints by 78 percent.

10:16:35 And even if it's one patient who's going to be harmed because of a design flaw that a company is aware of, isn't that one enough for a company to do something? Why should it be so many? And why should it be that they know there are people out there who still haven't been asymptomatic before you do something about this filter?

10:17:00 Well, the technology, they knew it was available. And recall Dr. Ciavarella. He's the one that said 1 to 5 percent of complaints are all that are actually reported, and he also questioned, he wondered one day when he was receiving the mounting complaints of the G2, he came in his office in December of 2005, and he wondered and he sent an e-mail, why wouldn't doctors be using the Simon Nitinol which virtually has no complaints.

10:17:21 Now, if anybody should know about a filter's history in Bard, you would think it would be the medical director.

10:17:40 And that certainly is a reliable source to know how their products compared to each other.

Bard was aware of the technology back in 2006. This is an e-mail, it's Exhibit 2249, from Natalie Wong. Remember she is the one that did the DFMEA analysis. And Bard knew

10:18:10

10:18:19 about a filter out there, the Greenfield, that had caudal migration problems, and they stopped it by flipping the hooks.

You heard from Bret Baird, who ran marketing at some point in time. And he, again, had no idea what Bard was not 10:18:44 sharing with doctors.

Another factor is the technology that's available. And again, Doris Jones received her filter on August 24, 2010. This is a memo dated April 27, 2010, where they talk about the name change was to address and break the baggage associated 10:19:14 with previous versions despite the fact that the new iteration was the same as the G2X in every way but one. And speaking of aggressive marketing, the name change was well received and the strategy worked. The suits won again.

So what do you do? Well, if you don't have the 10:19:44 technology to fix the problem, you need to stop selling it. You heard that. And that's testimony that we heard from some of even Bard's own experts.

The sales force themselves believed that the Simon Nitinol was the safest filter. This is an e-mail from 10:20:04 Jason Greer. The sales force was hearing from the doctors about how upset they were. The sales force had a bad product, and they made money by making sales.

So here was Jason Greer dealing with the G2, the baggage of the Recovery, and was reminding everybody that they 10:20:22 still had the Simon Nitinol filter.

10:20:24 And the Simon Nitinol filter, as evidence showed, was a good filter. The salespeople believed in it. Dr. Ciavarella believed in it. Bard believed in it.

It changes when people are watching. That changes 10:20:37 when they come to court. Because then here they were trying to impress that Simon Nitinol filter was having problems and that maybe it wasn't the model filter they contended it was back in time.

You heard from Dr. Grassi who talked about the SIR 10:21:08 guidelines. And in terms of compliance with industry standards, the 2001 guidelines had nothing to with retrievable filters.

And when you look at factors about compliance with industry standards, think about the testimony you heard 10:21:23 yesterday from Chad Modra, and remember the importance of postmarket surveillance and how important it is for Bard to address complaints. To collect them and report them. And to report them accurately to the FDA, who relies on that. It's an honor system. And to report that because they know doctors 10:21:48 rely on it.

And yet the FDA came in and found examples where Bard was calling serious injuries, for example, the Eclipse, that resulted in pericardial effusion to the patient, they call that a malfunction.

10:22:09 Make no mistake. This was not an audit, it was an

10:22:13 inspection. And make no mistake, Bard was cited for violations. And Bard didn't voluntarily go about revisiting its complaints. It had to. Because if it didn't, the FDA had the power to shut it down and to put serious sanctions on it.

10:22:43 And remember, and we talked about this a lot, the FDA isn't here. The FDA's not making decisions in this case. And the FDA cleared this device. It was an honor system. We're an honor system here. The difference is here, unlike the FDA, you get to see all the evidence. The difference here that's

10:23:07 different than the FDA is that you hear from witnesses who are put under oath who have to tell their story in court.

Bard has a duty regardless of what the FDA tells it, and the FDA expects it to do things. It can do what it wants to do to protect patients without the FDA requiring it to do

10:23:37 so.

Another factor is common knowledge or expectation of dangers. And you've heard a lot about these IFUs, but they talk nothing about the rates of complications, and neither does Bard's marketing.

10:23:54 The information, the Information for Use documents talk -- did the same thing that Bard did with the sales force. And what Bard did in this trial is what it did to the medical community, just our filters all fail.

We believe that we have established the evidence for

10:24:22 failure to warn. Again, the IFU does not warn physicians

10:24:30 that -- and does not state that migration can cause fracture. It doesn't provide rates of migration. And what this IFU did, you heard from Dr. Hurst, is it presents a laundry list that dilutes the importance of Bard's complications.

10:24:50 I'm losing a lot of paper back here.

Bard talked in its brochures about electropolishing when it promoted the electro- -- excuse me, the Eclipse. But recall that it's own vice president of research, Ms. Raji-Kubba, testified that electropolishing did not

10:25:27 improve fracture resistance.

And when you look at the failure to warn, the warning is inadequate because Bard has done nothing to warn doctors about patients -- about patients being asymptomatic. Bard has done nothing to tell doctors what they know about the history

10:25:50 of its filters. Bard has not contacted the medical community, and instead of saying our filters fail like all the rest, instead of suggesting you may want to think about removing it, why didn't they say we know the Eclipse is just a G2X and the G2. We're doing the right thing today, you need to get your

10:26:16 patients back in here, back in to see you, and look to see if they have a failed filter that they just don't know about. And Bard never warned about that.

And we know that because they have a history because that's exactly what Dr. Murray Asch asked them to do.

10:26:39 We believe the evidence has shown that Bard breached

its duty to warn.

And Dr. Avino certainly did not -- and the evidence has shown he did not get the warnings about Bard's history. He wanted no know about the 2003 and how it lacked solid clinical evidence. And he wanted to know that there was a significant difference between competitor filters. And you heard him testify he wasn't given that information.

The evidence has shown Bard's false and misleading marketing.

I'm picking up the pace because my time is running out and I still have some things to talk to you about.

But we believe that the evidence has shown that by omissions and by stating things about electropolishing, we have shown that Bard has misled the public and users of the Eclipse.

Bard continued to sell knowing that if it just fixed the problem, it could reduce failures by 78 percent.

I'll move forward.

Remember Natalie Wong, what she found when she did her study. She found that the G2 caudal migration was an unacceptable risk. That's when it's time to stop.

This is how the suits won, by aggressive marketing. And they were proud of it.

Now let me talk to you quickly about Doris.

Doris told a very touching story, and so did Alfred,

10:28:41 about her father. About how he helped people in the neighborhood by fixing cars. Doris learned from that. And that's what she does. She is intent to every day help her daughters have better lives by taking care of her
10:29:00 grandchildren and giving her daughters peace of mind.

What she can't --

My papers are falling back here.

The problem Doris has is that she is haunted every day by this Eclipse filter. It steals her joy. And now Bard,
10:29:43 Bard who made a choice to put all the risk on her, has placed Doris in a difficult predicament. Because now she's heard about surgery, but that's a scary thing too. So her choice is that she live with the filter strut, and the defense expert said she should. But they haven't come forth with any
10:30:10 evidence or any studies saying that that is a safe thing to do. And they know it's not.

Bard understands the issue with asymptomatic, and that's why they want to stay away from it. Because a filter in the pulmonary artery, as you heard, is a dangerous thing.
10:30:27 And so is the procedure. Now, you heard testimony about the procedure.

And I need to talk to you about your verdict. And I have been -- and I have learned from doing this that juries often want to know what other juries have done in cases like
10:30:48 this. And we can't do that. But what I can share with you is

10:30:54 my 31 years of experience and give you some guidance, but this is your decision.

Doris has had this strut in her since 2010. It steals her joy. It's there every day. It's causing her 10:31:10 mental anguish.

Now, think about this. If Bard was in a lawsuit where it was trying to collect on some type of a patent infringement and its damages were 25 million, it wouldn't think twice about going after the offending party for that 10:31:27 amount.

But this is more serious because this is a human life. This is a human being. This is a patient. And Bard knows there is a lot more out there and they know just how serious it is. So they distance her -- themselves -- they 10:31:45 distance themselves from Doris and people like her.

But think about this: Do you think that if somebody walked up to Doris and said I will give you $10 million to have this filter strut in your pulmonary artery, and I want you to take the risk for that. Not knowing moment to moment, 10:32:09 day to day what's going to happen. Do you think she would do that? Of course not. Nobody would.

But she has it. And she has that fear and she has Bard in her every day and she can't get rid of Bard. And so she's got a choice to make. So the question is if she goes in 10:32:32 and has a surgery, there's been no testimony by anybody that

10:32:34 the surgery will be successful. Let's suppose she does that in a year. So what has the last four years done to her? It stealed her joy, changed her life. Made her think about this every minute, every moment worried.

10:32:54 And I would suggest for that that a reasonable compensatory verdict is $2 million. $2 million. That's how important life is. And Bard knows it. That's why they want to distance themselves from Doris.

But if she decides or they find that she can't have 10:33:17 the surgery, or she just is in this predicament where she doesn't to go through that risk, Bard has already put her through enough risk. Her family's important to her and she has to stay strong. So she lives the rest of her life with the fear of this strut in her pulmonary artery every day. 10:33:43 Every moment. Every moment that she is doing something, she has to think about this and worry about it.

I would suggest that if this filter's going to be in her for her lifetime, a verdict in the amount of $6 million is reasonable.

10:34:03 And what you can do as jurors is stop this. And you can fix this too. We talked about punitive damages and we believe the evidence has shown that Bard has acted with willful misconduct. Its aggressive marketing has completely been a choice to disregard the safety and the risks that it 10:34:38 imposes on its patients. And that warrants punitive damages.

10:34:44 So when you get the verdict form, there are going to be boxes. We believe we have proven every element of every cause of action. We're going to ask you to check that we did.

And then for damages, this is your call. We're going 10:34:59 to ask you to award either 2 million or 6 million or whatever you decide is reasonable. And then we're going to ask you to check the box that, yes, Bard should be subjected to punitive damages.

Because here's the thing, Bard needs to hear. And 10:35:22 they need to hear from an Arizona jury that an Arizona jury is not going to tolerate this. That here in Arizona, we believe patient safety is important. We believe that if a company says they're testing things, that they're doing it for the real world. And when they find out in the real world that the 10:35:40 filter is not behaving themselves, they get the technology implemented right away. When they decided to do it, they were able to do it fast.

That a company like Bard should not act in self-interest to keep itself in the market and protect its 10:35:58 reputation by doing a fake out with the Eclipse to get rid of the baggage. And we think the only way that message is going to get across is with the verdict that we discussed, and then a punitive award to make them stop.

So if Mr. North thinks that what I've suggested to 10:36:24 you as a reasonable range -- I hope he tells you what he

10:36:28 thinks is a reasonable range.

But we have now been with Doris, my team and I, for two years, and her family. And we've come to know her. And we've learned about her case. And we are in the courtroom 10:36:48 today. It is a justice and there -- this is a house of justice and it is sacred, and this is where the FDA has nothing to say. This is where Arizona juries can make a difference.

So now I have to, on behalf of my team, turn Doris 10:37:10 over to you for you to make a decision. And, remember, you won't forget this case. Someday, somewhere, you're going to be outside enjoying the Arizona weather and you're going to wonder, how is Doris doing.

And just remember this, this is her only day in 10:37:29 court. But I also know this, I'm turning her over to you and that's because we trust you. And I want to thank you for your time.

Thank you.

THE COURT: All right, ladies and gentlemen, that 10:37:44 leads us to the break. We will plan to resume at about five minutes to the hour. We'll excuse the jury at this time.

(Recess was taken from 10:38 to 10:55. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

10:57:02 Mr. North, you may proceed.

10:57:03 MR. NORTH: Thank you, Your Honor.

May it please the Court, ladies and gentlemen of the jury.

First of all, I would like to thank you. On behalf 10:57:19 of my colleagues, Ms. Helm and Mr. Rogers, we thank you. And on behalf of our client, Ms. Camarata, and all of the other folks, men and women of Bard who you met and who did you not meet, we thank you.

We all recognize the imposition it is on your lives 10:57:37 to come and spend three weeks in this courtroom to resolve this dispute between Mrs. Jones and Bard.

We appreciate your attention. You must have been one of the most attentive juries I have ever seen. Your dedication and your commitment to come here every day. I 10:57:54 think I speak on behalf of everyone in this courtroom in thanking you for that. Because we could not resolve this dispute without your help.

I told you at the outset of this case in opening statement that, in my belief, Bard stands wrongly accused in 10:58:12 this courtroom. After three weeks of trial and after the last 50 minutes of Mr. O'Connor's opening -- closing argument, I believe that more than ever.

We simply would not be here and would not have spent the last three weeks here if we believed the story 10:58:30 Mr. O'Connor told you. This case would have resolved a long

10:58:36 time ago.

Ladies and gentlemen, at the outset of this case I asked you to please keep an open mind. Because the plaintiff has the burden of proof, they went first with their evidence. 10:58:48 We could not put on our evidence until they completed theirs. We asked for you to wait until you could hear what we believed would be the whole story, and we trust you did.

Before talking about the issues in this case, though, I would like to talk about a few things that I believe are not 10:59:08 at issue, some of which we've spent a great deal of time talking about, but I believe simply are not at issue in this case.

Now, the first one is something that I think we would all agree with. What is not at issue is Mrs. Jones. No one 10:59:29 is blaming her for her complication. We are all human beings. We all have sympathy for her. We have sympathy for what has happened to her. We have sympathy for the medical conditions she fought with before both before and after the implant and the complications with the filter. No one is here trying to 10:59:51 disparage Mrs. Jones. She's simply not at issue here.

But there are a number of other things that are also are not at issue, I submit. And that is the fact that this case is about an Eclipse filter.

Mrs. Jones received and was implanted in August of 11:00:14 2010 with an Eclipse filter. She was not implanted with the

11:00:19 Bard Recovery filter, first generation. She was not even implanted with the G2, the second generation filter.

And yet 95 percent of the evidence you have heard from the plaintiffs in this case, 95 percent of Mr. O'Connor's 11:00:38 closing argument concerned these two filters. I sat there and timed it, ladies and gentlemen. We were ten minutes into his closing argument before he mentioned the Eclipse for the first time.

And yet during that ten minutes he mentioned Recovery 11:00:55 at least 20 times.

You have to ask why. Why have we spent the better part of three weeks listening to evidence about the Recovery filter and why haven't we heard more about the Eclipse filter?

We heard so much about the Recovery filter even 11:01:16 though it was last sold in 2005. Five years before Ms. Jones ever received her implant. And we heard all of this about the Recovery filter even though it was specifically designed -- and you heard the engineers explain it to you, it was specifically designed to address issues first seen with the 11:01:39 Recovery filter, which was the first retrievable filter introduced to the marketplace, Bard assessed the clinical experience of that filter and specifically set out with the G2 to make the Recovery filter -- or the filter more migration resistant and more fracture resistant.

11:01:58 And yet despite all those changes, the plaintiffs

11:02:01 have spent most of our time here talking about a first generation filter that had been off the market long before Mrs. Jones received hers.

What is some of the evidence we have heard that had to do only with the Recovery filter?

We heard about Dr. Murray Asch. We heard ten minutes of discussion of Dr. Asch this morning in the closing argument. Dr. Asch did the clinical study on the Recovery filter. He has had no involvement with Bard in 13 years. He's had no involvement with Bard for five years before Mrs. Jones' procedure.

They brought one of our engineers, Alex Tessmer, and examined him for more than an hour about tests performed on the Recovery filter in the early 2000s.

They showed you videotape of Janet Hudnall concerning the marketing of the Recovery filter.

They showed you Jason Greer, a sales representative, talking about complications with the Recovery filter.

This case is not about the Recovery filter. This case is not even about the G2 filter. Even though the G2 had much lower complication rates than the Recovery filter.

Ladies and gentlemen, this case, and what is at issue in this case, is the Eclipse filter.

What else do I submit to you is not at issue in this case? That's the Simon Nitinol filter. The plaintiffs have

11:03:49 spent the better part of the three-week trial trying to promote to you the Simon Nitinol filter as a far superior filter to any of the retrievable filters and as a viable alternative that should have been implanted in patients like
11:04:04 Mrs. Jones.

But what did the evidence say in that regard? The evidence showed that her doctor, Dr. Avino, wanted to implant a retrievable filter. If that's the case, the Simon Nitinol filter is not a candidate.

11:04:26 You heard the testimony yesterday of Dr. Scott Trerotola from the University of Pennsylvania. He said the folks in his practice call it is Simon frightenol.

You heard the testimony of Dr. Christopher Morris, an interventional radiologist with a long history of use of all
11:04:48 sorts of filters. And he said that contrary to what the plaintiffs have claimed in this courtroom, there are a number of complications that have been associated with the Simon Nitinol filter.

What is the clearest evidence, though, of why the
11:05:00 Simon Nitinol filter is not at issue and is not a viable alternative? I would submit it's the chart we showed you yesterday morning with Mr. Rob Carr, showing the sales over the last 13 years. The red line are Bard's retrievable filters. The blue line the is Simon Nitinol filter. The fact
11:05:25 of the matter is that doctors in this country, just like

11:05:29 Mrs. Jones' doctor, Dr. Avino, do not want to implant permanent filters. They want retrievable filters. And because of that, the Simon Nitinol filter became a dinosaur. It's no longer on the market for that reason.

11:05:44 In today's medical world, an old permanent filter like the Simon Nitinol filter is not a viable alternative.

Ladies and gentlemen, I would submit that another thing that is not at issue in this case is the FDA warning letter. I am really glad that you got to see this letter

11:06:08 because I think it disproves what we have heard from the plaintiffs throughout this case. They tell that you the FDA clearance process is simply an honor system. They try to make it sound like the FDA just rubber-stamps these applications, contrary to all the evidence that shows to the contrary.

11:06:32 What did the warning letter show you? And the testimony of Mr. Modra? Bard Peripheral Vascular has been inspected four times by the FDA on routine inspections in the last decade alone. Every aspect of the company.

You saw yesterday where Mr. Modra explained when the

11:06:55 FDA inspectors came, they want to see the design files for these filters and other devices. They're looking at complaint handling. They're looking at everything.

This is not an honor system. This is an agency proactively keeping track of medical device manufacturers.

11:07:14 Bard and all the others.

11:07:17 It's not a rubber stamp. But what also I thought that letter demonstrated is that despite four inspections over ten years, all the FDA found to complain about were some technical reporting issues on complaint files. Not a single
11:07:39 word about the design of the Bard retrievable filters, not a single complaint about the warnings with the filters.

The FDA warning letter, the only one issued after four inspections over a decade, didn't even issue until five years after Mrs. Jones received her implant. It concerned
11:08:08 reporting issues.

You heard the testimony of Mr. Modra. There was not a single failure cited by the FDA of failing to report to the FDA an event that involved a patient injury. Not a single one.

11:08:29 If you read the letter you'll even see that it's not official regulatory action on page 10. It is merely a warning. That's why it's called an FDA warning letter.

And it had nothing to do with the design or the performance of the Recovery filter, the G2 filter, the Eclipse
11:08:49 filter. Nothing to do with any of that.

Ladies and gentlemen, I submit to you that is simply not an issue in this case.

Now, ladies and gentlemen, I'd like to talk to you about a phenomenon I believe we have seen throughout this
11:09:09 trial.

11:09:11 Here is the real world we all live in. The jobs we go to, the schools we send our children to, the spouses and loved ones we spend our time with. There is a real world out there. Where we use our common sense every day to go about
11:09:27 our lives.

Unfortunately, I submit to you, there's also a litigation bubble which sometimes can occur in courtrooms and has occurred in this courtroom. It is an artificial world where evidence becomes slanted. Where paid experts try to
11:09:47 change or alter the evidence to fit the theory of an attorney who's hired them. It's a litigation bubble, and it's very different from the real world.

And I'd like to talk to you a few minutes about how I believe that litigation bubble has played out over these three
11:10:05 weeks.

But first let's mention a couple of things that are clearly the real world. Where everybody, whether it's the doctors that treated Mrs. Jones or the experts on either side that came in here agreed, every single witness agreed that
11:10:26 Mrs. Jones needed a filter.

You'll recall the evidence. She had gastric bleeding. She needed surgery for the gastric bleeding. She had only recently had a deep vein thrombosis and she was at a high risk of a pulmonary embolism as a result. She could not
11:10:47 be put on blood thinners or anticoagulants because she had to

11:10:52 have that surgery. So the only alternative, treatment alternative, for her to protect her against a potentially life-threatening pulmonary embolism was to implant a filter. And every single doctor that testified in this case agreed she 11:11:12 needed that filter.

And, interestingly, every single one of these doctors testified on both sides that they still implant filters. They still believe these devices are important for those patients who cannot be on anticoagulants.

11:11:36 There's another point where all the witnesses seem to embrace the real world, and that's that they all acknowledged that these devices have complications. Not just Bard's filters, but all filters. You heard it over and over, like a mantra, from every witness admitting every filter migrates. 11:11:59 Every filter fractures. Every filter perforates. And every filter tilts. It is a real world reality.

And no matter how hard the men and women at Bard, through six generations of retrievable filters, have tried to completely eliminate those risks, it hasn't been able to be 11:12:23 done. Nor has any other manufacturer been able to do it. And every witness recognized that that is a fact in the real world.

But, ladies and gentlemen, there are other areas in this trial where I submit to you the litigation bubble has 11:12:41 prevented -- presented an entirely different story than the

11:12:45 real world evidence.

Let's look, for example, at the question of removing the strut in Mrs. Jones.

The plaintiffs say there is a need for intervention. 11:12:59 Either a percutaneous procedure or open surgery, even, to remove that strut.

They came into this courtroom, into a litigation bubble, and told you that even though they had never examined Mrs. Jones as a patient.

11:13:18 They reach that conclusion and told you that even though they admitted -- this is Dr. Hurst and Dr. Muehrcke -- they admitted that they had not even reviewed all of her medical records and all of her scans.

Well, what's the real world? The real world is what 11:13:40 the doctors that have examined her, the doctors that have treated her testified to.

Dr. Nelson said that strut wasn't going to go anyplace. And it had probably been there for some time without causing any ill effect.

11:14:03 That was the real world. The doctor that treated her said that strut is fine, it's not causing her any problems and it isn't going to go anyplace. And she treated Mrs. Jones. She read the records.

What is the plaintiff's rejoinder to that? 11:14:24 Mr. O'Connor comes up or has the experts say she wasn't

11:14:27 qualified.

What evidence do they have and what standing does Dr. Muehrcke have to come into this courtroom and claim that a physician, an interventional radiologist with years of 11:14:40 experience, somehow isn't qualified or able to remove a strut and therefore has thrown up her hands and suggested, ah, she can just keep it. That's not the real world.

The real world is that the doctor that treated her said that strut is fine. Not the doctors that came in as paid 11:15:01 experts in a litigation bubble.

Let's talk about another area where the reality is -- the real world and the litigation bubble diverge here, and that's regarding symptoms.

Dr. Muehrcke and Dr. Hurst, the paid experts brought 11:15:20 by the plaintiff, got on this witness stand and said she presented to the hospital, Mrs. Jones, with arm pain, and that arm pain was caused by that strut.

They testified to that even though they had never examined or treated Mrs. Jones, even though they admit they 11:15:42 have not reviewed many of her records and scans, and even though she had previously experienced radiating arm pain.

And that's totally contrary, again, to the evidence in the real world where the testimony of Mrs. Jones' own doctors indicated that she did not have symptoms related to 11:16:09 that strut.

11:16:10 And the medical record, you see it, it's an exhibit in this case. It attributes the arm pain to an iron deficiency because -- remember, because of her bleeding, Mrs. Jones had a long history of anemia.

11:16:28 In the real world there's no association of that strut with any symptoms in Mrs. Jones. Only in the litigation bubble do we have that allegation.

Ladies and gentlemen, I would submit to you that the selective use of individual documents out of over a million

11:16:53 produced in this case, taken out of context by the plaintiff and the plaintiff's experts, is probably the clearest example of where the litigation bubble differs from the real world.

How many times did we see this report prepared in 2006 by Natalie Wong displayed, mentioned, referenced by

11:17:24 Mr. O'Connor and his colleagues? Constantly.

The litigation -- I mean the migration risk with the G2 filter is unacceptable, they said, over and over, and that Bard had acknowledged that.

What they did not mention is that this was a

11:17:44 report -- and look at the column, first column that's highlighted. This is a report where Mrs. Wong is analyzing 13 events. 13 events. And look at the second column. Out of 8,924 units sold at that time. 13 events.

But put that in context. We then tried to bring some

11:18:13 of the other documents to your attention. The company just

didn't come up with this conclusion of unacceptable based on 13 events and do nothing. What did Bard do as a responsible manufacturer? It conducted a failure investigation and issued a report as a result. The medical director conducted a health hazard evaluation and issued a report. Bard went out and met with the leading interventional radiologists in the country and had a focus group to discuss the clinical consequences of caudal migration.

Bard conducted a risk/benefit analysis. Bard advised the FDA of its finding of the number of events, 13, and of how the criteria was altered because of the fact that the original criteria on what was acceptable was based on a fear of cephalad migration, filters going to the heart, and didn't take into account the much less serious consequence, as the doctors had told them, of caudal migration.

Bard told and explained that to the FDA on three different occasions, at least.

That's the real world, ladies and gentlemen. Not taking one document and one statement of unacceptable based on 13 events out of context. But, instead, looking at the whole story of what a responsible manufacturer does when it sees the slightest blip on the screen, 13 events, and all those resources poured into it, the situation, to investigate.

We heard about another instance of the litigation bubble just in Mr. O'Connor's closing argument this morning.

He talked -- he showed you another memo taken out of context where Mr. Little is saying let's call the new filter the Eclipse so we can have a break with the baggage.

But he didn't mention the context to you. The context, which you heard yesterday in Mr. Little's deposition, is that what that baggage was was bad publicity in the marketplace concerning Bard's G2 filter because of lawyer advertising on a website called filter.com -- filterlaw.com. That was the baggage. The publicity of lawyer advertising.

Here's another litigation bubble, I submit to you. The notion of a cascade. How many times have we heard over the last three weeks, and particularly from the plaintiff's experts, that with Bard filters there is a cascade of complications.

First of all, in the real world -- well, the plaintiffs have said that, that there is a cascade of complications, even though there is no evidence of that in this case. There's no evidence of perforation. There was only a four-degree tilt, like 10:02, the doctor admitted. Just barely tilting. There was no real evidence of migration.

Dr. Muehrcke, the plaintiff's attorney -- expert, even got up and testified, well, I didn't see migration on the films but I just assumed it happened. He called it micro movement.

But yet they said there was this cascade of

11:22:10 complications.

But let's look about the real world. Even Dr. Hurst, one of the plaintiff's experts, admitted he had never heard the term "cascade" outside of the courtroom. Never.

11:22:28 Dr. Clement Grassi, the fellow of the SIR who testified, said he had never seen this so-called cascade referenced in the medical literature and he's never heard this so-called cascade mentioned at any medical meetings.

Some of the clearest proof, ladies and gentlemen, I 11:22:53 submit to you, of how this cascade is nothing but something in this litigation bubble is this very exhibit that the plaintiffs introduced yesterday. It is a summary that they prepared where they tried to analyze Bard's complaint files, the reports of adverse events and figure out the number of 11:23:19 complications.

And I urge you to go look at this because I think it demonstrates more clearly than anything that a cascade does not exist.

The data shows there were 66,000 Eclipse filters 11:23:43 sold. But, look, this is fracture data. Look at the Eclipse column. Out of 66,000, look how few had any combination of fracture and another complication. That's their expert's whole theory of cascade, is that you have these multiple complications. Tilt, plus fracture, plus perforation, plus 11:24:07 migration, or some combination thereof.

11:24:11 Look at how few, out of 66,000 sold, had any combination of fracture and another complication.

The same thing with migration. Less than five out of 66,000 sold with multiple complications.

11:24:41 I think I skipped the perforation.

Same thing with perforation. Less than ten out of 66,000 sold with multiple complications.

That was the migration.

And then the tilt. The same thing. Very few people

11:25:10 having multiple complications.

Now, don't get me wrong, these are not just statistics. Every single place where there is at least one there represents a human being. I understand that. And the people at Bard understand that. And they're striving to come

11:25:30 to the day and to be the first manufacturer where every number there is zero. But they haven't been able to reach that point yet.

But the fact of the matter is only in a litigation bubble is there this notion that Bard filters suffer from some

11:25:49 huge cascade of multiple complications.

In the real world, based on the very data the plaintiff's attorneys themselves prepared to submit to you, that's just not the case.

Let's talk a little bit about another area of the

11:26:08 litigation bubble, as I would describe it, and that's the

11:26:12 plaintiff's witnesses and experts. And let's start with one of the witnesses that Mr. O'Connor talked about at length. Dr. Murray Asch.

I submit to you there is no clearer evidence of a 11:26:32 litigation bubble than Dr. Asch and what he came to this courtroom to try to tell you. He admitted that he's testified and been paid by these plaintiffs' lawyers in the past. He was only involved with the Recovery filter. Prior to 2005.

He claimed that the complications in his study, two 11:26:58 complications, required further evaluation. Yet he admitted when I cross-examined him that he had published an article to the international medical community in which he claimed there were no significant complications in his study because both of the complications were asymptomatic.

11:27:18 When I challenged him as to why he could testify to this jury that he did not think this filter was ready to be used because of these very concerning complications, and yet tell the medical community internationally that there were no significant complications in his study, what was his response? 11:27:42 He claimed he was downplaying them. Only in the litigation bubble does someone come and try to tell you I told everyone there was a big problem, oh, but when I told the medical community this in my literature I was just downplaying it.

Ladies and gentlemen, he came and testified that he 11:28:02 felt betrayed. And Mr. O'Connor just mentioned that, as if

11:28:07 Bard had done something terrible to this doctor. He felt betrayed because he did not know we were going to use his study to obtain clearance from the FDA regarding the Recovery filter. How could he say that outside of a litigation bubble?

11:28:29 Look, ladies and gentlemen, at what he wrote and he admitted writing for the FDA. He says, "It is with great pleasure that I write this letter in support of Bard's application for approval of its Recovery IVC filter system. I strongly believe that the development represents one of the

11:28:51 most important advances," and he concludes by saying there is a definite need for this device.

This is the real world. Dr. Asch wrote a letter to the FDA seeking to support the clearance of a device that he comes into this litigation bubble, being paid by the

11:29:10 plaintiff's attorneys, and says this device wasn't ready and I'm betrayed because they presented my study to the FDA. He knew. He admitted he knew.

Then there was the plaintiff's expert, Dr. Garcia, came very much at the beginning of trial. He -- and he wasn't

11:29:36 the only one called by the plaintiff. He's also an expert in the Cook litigation against another manufacturer of IVC filters.

He admitted that Mrs. Jones was a perfect candidate for the filter and that he would have prescribed a filter for

11:29:52 him herself.

11:29:54 He tried to say that filters may not be effective in treating pulmonary emboli. And he admitted that he had published an article noting that IVC filter placement reduces risk.

11:30:08 I posed this question when I was preparing this slide. Why does the plaintiff stand up here, plaintiff's attorney stand up here repeatedly in questions to witnesses, in argument to you, and try to imply that IVC filters don't have a benefit when their own experts are publishing saying

11:30:31 that these devices reduce risk.

Dr. Garcia also tried to say there's a future risk from the strut in Mrs. Jones' pulmonary artery. But he admitted that he had not looked at any of the films. And he could not cite a single medical literature or article that

11:30:54 suggested a risk. And that's no surprise because there is no medical article. And they have not brought one in to say there is a risk.

Only in a litigation bubble, ladies and gentlemen, could an expert come in and try to question the effectiveness

11:31:14 of a device that he has previously published articles on that said it was effective, and also admit he would have placed the device himself in this patient, Mrs. Jones.

Then there was Dr. Muehrcke. He offered broad opinions condemning Bard's filters. And then admitted that he

11:31:37 reached his opinions after reading only 24 of the 1 million

11:31:43 pages of company documents that have been produced in litigation. He did not support the plaintiff's theory of a cascade of events here because he admitted there was no perforation and he admitted he could not see migration. He
11:32:02 admitted the tilt was minor.

Then there was Dr. Hurst. He exemplified the paid expert, I submit, in a litigation bubble.

He came in and testified about IVC filters even though he's never published anything on the devices. He
11:32:23 admitted that he advertises his services as an expert witness in IVC filter litigation.

Yet he agreed, as everyone else did, that Mrs. Jones needed the filter. He also, although he tried to back away from his previous testimony, he acknowledged that he had
11:32:42 admitted in the past that complication rates with these filters below 1 percent are acceptable because these complications are unavoidable with all filters.

This, to me, ladies and gentlemen, was one of the most amazing examples of what can happen in the litigation
11:33:03 bubble.

Dr. Hurst was paid by the plaintiff tens of thousands of dollars to come into this courtroom and condemn Bard filters. To give opinions in support of the theory of the case advanced by Mr. O'Connor and his team. And yet he had to
11:33:25 admit that he himself had used Bard filters throughout his

11:33:30 career and had even implanted a Denali filter, the latest generation, two weeks ago.

How do you come to the stand as a witness and condemn a company, claim they've acted inappropriately, claim that 11:33:49 their products are defective, and admit you have used those products on patients that you treat?

Only in the litigation bubble could an expert doctor come and do that.

Ladies and gentlemen, let's talk a few minutes about 11:34:15 plaintiff's burden of proof here. I would like to submit to you what we believe the evidence shows on what really is at issue here. And that is whether the Eclipse filter, not the Recovery, not the G2, but whether the Eclipse filter is defectively designed and, number two, whether the warnings 11:34:34 with the Eclipse filter were adequate.

This is the plaintiff's burden of proof to show a defect in the design, a defect in the warning, to show that one of those defects, if they prove it, was a cause of Mrs. Jones' injuries. And then to prove her damages.

11:35:02 Mr. O'Connor alluded to this and the judge instructed you on this. The key issue on design defect is risk/benefit. This case is governed by Georgia law because that is where Mrs. Jones resides. And under -- in Georgia the test for a design defect is whether the risks outweigh the benefits. And 11:35:29 the jury instructions that you were given and that you will

11:35:32 have with you talk about that. All the factors that you look at in weighing the risks with the benefits.

I submit to you, ladies and gentlemen, that the plaintiff's evidence trying to skew the risk/benefit equation 11:35:51 in their favor is a classic case of no good deed goes unpunished.

This is a story of continuous improvement. A company that spent more than $18 million in designing these filters and improving them. In over a 13-year period, developing six 11:36:15 generations of what all of the witnesses admitted was a revolutionary device because it was retrievable and could be left in the body for long periods of time.

The plaintiff's attorney like to cherry-pick evidence from that continuous improvement cycle. Just because 11:36:36 engineers are talking about caudal anchors in an effort to reduce those complications, they're like, well, you should have put it on right then.

Well, you heard the engineers discuss the development process. You heard Mr. Randall yesterday show you not only 11:36:57 all of these projects, but all the projects, for whatever technical reasons, couldn't come to fruition because they ran into technological issues on some of them.

This is a case of continuous improvement, six generations of a revolutionary device over a 13- to 15-year 11:37:18 period.

11:37:18 This is what the judge will or has instructed you as far as the risk/benefit test. You have to balance the inherent risk of harm against the utility or benefits of the product design.

11:37:38 And you also have to determine whether Bard exercised reasonable care in choosing the design for a product.

Ladies and gentlemen, I would submit to you that the most powerful evidence on this issue, whether these designs, or this design, was defective, comes straight from the words

11:38:04 of the FDA.

I urge you if there's any question in your mind to look at Exhibit 5877 when you get back to the jury room.

5877 is the memo written by an FDA official. In 1996, when the agency was deciding whether to down classify

11:38:29 filters from Class III to Class II, and the agency determined that they were going to down classify these filters despite the fact that there were clearly risks associated with them.

And they recognized that the complications or risks were potentially life-threatening, but that the disease these

11:39:01 filters is supposed to treat, pulmonary embolism, is also life-threatening. And even aware of the very risks that the plaintiff's attorney is complaining about in this courtroom, even aware that those risks will occur, the FDA determined that it was not an unreasonable risk of illness and injury

11:39:28 because of the benefits of these devices. And the agency made

11:39:31 that risk/benefit calculation even knowing that migration could occur and reporting that migration with these devices could occur between 6 and 53 percent of the time.

Also noting, as all the evidence has indicated here, 11:39:52 that minor filter migration is commonly reported and does not appear to be associated with clinically significant events.

In other words, the agency decided to down classify these filters even knowing there was this significant risk of migration. And also knowing that there was a significant risk 11:40:16 of fracture.

The FDA noted that fracture is usually asymptomatic and requires no treatment. And noted that the incidents of fracture had been reported as 2 percent in the literature.

And despite knowing that that risk of fracture was 11:40:40 there, the agency determined that the benefits of these devices was sufficiently great and outweighed those risks so that the agency down classified the device.

And the FDA maintains that view.

We showed you that as recently as 2010, the FDA 11:41:00 issued a public health notice, directed to doctors, talking about the fact that people with retrievable filters need to be monitored to see whether the device is ready to be removed. And in that notification, once again, 14 years after the down classification, the agency recognized that there are long-term 11:41:27 risks associated with these devices. And those risks include

11:41:32 the very same things complained about by the plaintiff here. The risk of filter migration, fracture, et cetera.

Why is the FDA willing to accept these risks for these devices, including the Eclipse device? It's because 11:41:53 deep vein thrombosis and pulmonary embolism, as we all know and as we've all heard repeatedly over these three weeks, they kill people.

Estimates are that as many as 200,000 people a year die. And people like Mrs. Jones are particularly at risk of 11:42:16 this near possibly fatal event when they have had a recent deep vein thrombosis, as she had had when she received the filter.

And in this exhibit, which was introduced yesterday, the surgeon general noted not only is this condition a 11:42:34 potentially fatal condition that kills more people in this country than -- each year than breast cancer, AIDS, and other such things combined, but they also noted that IVC filters are a viable option for the treatment of this potentially fatal decision.

11:42:54 There is other evidence, ladies and gentlemen, as to the adequacy of the design of this filter and Bard's reasonableness in choosing that design. We stacked up -- electronically speaking, stacked up the tests. There are tests -- there is test after test after test after test 11:43:17 conducted first with the Recovery filter.

11:43:20 You heard Mr. Carr say the development process, first at NMT then at Bard, for the Recovery filter was roughly -- took six years. The tests are voluminous. If we printed out hard copies, God forbid, it would stack up to here. Test
11:43:38 after test after test.

And the testing did not stop with the Recovery filter. There were -- was an entire new battery of tests with the G2. And it continued with the Eclipse, another battery of tests. And at every step of the way, this data was shared
11:44:04 with the FDA.

And it wasn't an honor system. It wasn't a rubber stamp. You saw the letters from the FDA. Please explain the clot-trapping efficiency test. Please provide us data on that.

11:44:19 You heard Mr. Carr talk about how he had to respond to 17 questions from the FDA regarding one 510(k) submission. It was a back and forth throughout with the agency wanting to see this data, analyze this data.

Let's look at just a few of the specific tests.

11:44:44 When Bard was creating the G2 filter it was attempting to improve the fracture resistance of the Recovery filter. And the clinical data, real world experience out there among patients, show that Bard succeeded. The fracture rate on the G2 was much less than that of the Recovery filter.

11:45:05 And that was predicted in the testing. Look at the

graph there. On the right-hand side is the G2, on the left is the Recovery filter. The testing showed that Bard had succeeded in achieving its design aims.

Let's look at some of the testing for the Eclipse. The Eclipse was going to be electropolished. Again with the hope of improving fracture resistance.

Here is a test to determine or assess fatigue, arm fatigue. Look at what the test concluded. A 60 percent increase in cyclic arm fatigue life when compared to the G2X. Again, trying to build a better mouse trap. A new generation of filter. And to address and make the complication rate as low as possible.

Additional testing. This is arm fatigue comparison.

Look how many cycles in this test the Eclipse could go through before failure compared to the G2X. Something like an 80 percent improvement.

Here's another test. Looking at cycles to fracture. In cyclic fatigue testing. Look at the percentage improvement in fatigue life of the Vail, which was the code name for Eclipse, to the G2X. Depending on which category you're looking at, it ranges from a 77.4 percent improvement to 101 percent improvement.

So the plaintiff brings one expert into the litigation bubble to try to tell us that the Bard filter is defectively designed. You saw him early in the case,

11:47:14 Dr. McMeeking. We all enjoyed him with his Scottish accent.

But look at what Dr. McMeeking admitted. He is an expert for the same group of attorneys in litigation against Cook Medical about their IVC filters. And in that litigation 11:47:37 he has offered the same opinions he came and offered here about the design of the Cook filters. And the same criticisms in that litigation about the testing performed by Cook.

He admitted, ladies and gentlemen, that he had no experience with filters. He's never published regarding a 11:48:05 filter. He's never designed a medical device. He's never conducted any bench testing. Any bench testing.

He came and tried to tell you that the Bard medical device was defective. Even though he has no experience in designing a medical device, or in bench testing one.

11:48:32 And he's not developed or tested an alternative design. He threw out some vague ideas, but he hasn't tried to develop an alternative. He has no opinions as to complication rates. And he admits that electropolishing makes a difference. Even though he hasn't done any bench testing, he 11:48:55 had to concede that electropolishing the Eclipse filter had to make a difference.

In response, we brought to you Dr. Briant. And I've tried not to hold it against him that he gets so excited about science, as he told us. But he does. And he is a scientist. 11:49:17 And he conducted a lot of work in this case. He did a finite

element analysis.

But he made an entirely different set of assumptions than Dr. McMeeking did, because he said that Dr. McMeeking's assumptions weren't real world. They were derived for a litigation bubble.

All engineers in this field with these materials know that Nitinol is unique because it is superelastic. That's what gives it its shape memory. Dr. McMeeking did not even consider the superelastic nature of Nitinol in doing his calculations. Dr. McMeeking did his calculations on a single arm of the filter. He admitted that. Dr. Briant did his calculations involving the entire filter. Dr. McMeeking really did not take into account the effect of the surrounding tissue and what that would have on the forces exerted on the filter. He assumed that, Dr. McMeeking did, that an IVC is rigid. It is not rigid, like a pipe, in our anatomy. It is deformable and flexible.

So he made, Dr. McMeeking, a lot of assumptions that really aren't real world. They're litigation bubble assumptions.

And when you apply the real world assumptions as to how the body really acts and how this superelastic material acts, you come up with very different results.

Look at the chart on the right. The red are the forces that Dr. McMeeking calculated based upon his bubble

11:51:17 assumptions. The blue are the forces calculated by exponent. Based upon real world assumptions.

And Dr. McMeeking did not bring any analysis in here to show you. He did not bring a single calculation. He did
11:51:38 not bring a single printout from a computer program that he performed. He sat on the stand and said, trust me. This is what my test showed. Trust me.

Dr. Briant, as overeager as he is, brought you data, graphs, explained in great detail and showed you the evidence
11:51:58 of what those forces are when you apply real world and not litigation bubble assumptions.

And what was the icing on the cake with regard to Dr. Briant, in my view? It is that, unlike Dr. McMeeking, he did bench testing. He wasn't going to just do a finite
11:52:22 element analysis and not bring you the results, tell you to trust me, and then not try to verify it. He did a finite element analysis, and then recreated the conditions on the bench. That's a picture of his bench testing performed in Menlo Park, California, where he did this test.

11:52:41 And what did that bench testing that Dr. McMeeking never performed do? Look at how almost identical the two lines are on the graph on the right. The bench testing replicated and verified the validity of his finite element analysis. And that's something that Dr. McMeeking never
11:53:07 tried.

11:53:09 Also on the issue of design defect, when you weigh the risks of this product, you have to look at the guidelines for the Society of Interventional Radiologists, the SIR guidelines.

11:53:19 You heard Dr. Grassi, who actually was the initial lead author of these guidelines. Now, Mr. O'Connor stood up and said, oh, those only apply to permanent filters.

Well, they did in 2001, when they were first issued. But you also heard the testimony that they have been reissued

11:53:42 every couple of years. The last reissuance was in 2016 or '17. And all the reissued guidelines, once retrievable filters came on the market, applied to both permanent and retrievable.

So to try to discount these that they only applied to

11:54:00 permanent discounts reality. That's an issue only in a litigation bubble. In a real world these guidelines have been assessed, reviewed, and consulted by physicians throughout the country who implant both permanent and retrievable filters.

And what do those guidelines show? That in the

11:54:21 medical community it is understood and recognized that IVC filters have been reported to migrate between zero and 18 percent of the time. Penetrate between zero and 41 percent of the time. And for the -- most important for this case, IVC filters, not just Bard filters, all filters, have been

11:54:48 reported to fracture 2 to 10 percent of the time.

11:54:53 Now, on the design defect, I talk a lot about the FDA's role and its involvement, because that is important legally. Judge Campbell instructed you, and you can see the instruction where it says that in determining whether the
11:55:10 defect -- I'm sorry, the design was defective, you may consider proof of a manufacturer's compliance with federal or state safety and nonsafety standards or regulations. It is a factor to consider in deciding whether the product design selected was reasonable.

11:55:33 What is the evidence? This last three weeks have been replete with example after example after example of the FDA's review and consideration of data concerning all IVC filters and review and evaluation of data concerning Bard filters.

11:55:55 There is an FDA guidance that acknowledges that the risks and benefits to patients with these devices are well documented, but sets forth a lot of particular testing guidelines that we are supposed to follow.

And the evidence was that Bard did follow those
11:56:16 guidelines, submit that battery of tests. A battery of tests that was reviewed by the agency in detail.

The Recovery filter was cleared twice. The G2 was cleared by the FDA after reviewing all of this material four times. And on January 14, 2010, the FDA cleared the Eclipse
11:56:38 filter.

11:56:40 There has been a long history of compliance with the FDA's guidelines and guidance regarding the development of IVC filters. There has been a long history of compliance by Bard with everything the agency has asked in design, testing, and
11:57:04 submission. And that is, under the law, a factor for you to consider in whether Bard acted reasonably and in whether the benefits of the device outweighed the risks.

The evidence, as I indicated, also shows this wasn't a rubber stamp. These are just some examples we showed you of
11:57:33 when Bard would submit tests to the FDA as a part of these 510(k) submissions, and the agency would come back with questions.

This is an internal memo we obtained through the Freedom of Information Act where the agency is assessing the
11:57:51 testing for the G2.

Another one, the agency is assessing the animal studies for the G2 and making a determination that further information is needed, and they went back to Bard for that information. They ultimately concluded that the bench testing
11:58:10 was sufficient after all of this analysis.

As I mentioned earlier, in this dialogue with the FDA, the evidence also indicates that Bard fully disclosed its analysis of caudal migration with the agency.

And this has continued. You heard there were
11:58:37 numerous instances where Bard actually went to, I think it's

11:58:40 Silver Springs, Maryland, or close there, to the FDA headquarters, and met with the agency for various reasons. This was in January 7 of 2010. A major meeting where Bard went and discussed with the FDA the performance history of its
11:58:59 filters. And this was right before, right about the time the agency went ahead and cleared the Eclipse.

What did Bard show the FDA? This is a PowerPoint presented to the agency. Bard indicated the fracture and migration history of the Recovery filter and the G2 filter
11:59:22 year by year, presented all the data to the FDA. Did not hide a thing.

And what did the FDA do? A couple of weeks later it cleared the Eclipse, fully knowing about the complications reported with the earlier generations.

11:59:43 Ladies and gentlemen, the strongest evidence, in my view, as to the risk/benefit calculus with regard to the design of the Eclipse filter the numbers.

Look at the data that Mr. Modra presented to you yesterday. Now, quite honest, trying to be quite honest with
12:00:07 you, this data is not perfect. It's not exact. This data depends upon the reliability of the information the company receives.

But you also heard how thorough Bard is. Bard investigates every medical literature report of a
12:00:25 complication, every sales representative, every physician,

12:00:30 phone call, every SIR presentation at a conference. Any time the company hears of a complication, it investigates it, and that complication is included in this data that is tracked and trended. And it's the best available data we have.

12:00:48 The plaintiffs try to get around this data because this data shows that out of 66,000 Eclipse filters sold, only .17 percent were reported to have a fracture. Not 1 percent, .17.

We saw the SIR guidelines, 2 to 10 percent is

12:01:13 reported in the medical literature. This is well below .17. Even 1 percent, much less 2 percent.

So what if Mr. O'Connor's complaint is correct and these are underreported. Let's multiply that number by 10. .17 percent. If 90 percent of the adverse events are not

12:01:37 reported and you want to make that assumption, the fracture rate then would 1.7 percent. Still well below the 2 to 10 percent fracture rate reported for all filters in the medical literature.

Ladies and gentlemen, I submit to you that this is

12:01:57 the most powerful evidence out there. They want you to believe that Bard filters have high complication rates. The data just does not support that. And they don't have data that contradicts that.

And, also, this data shows you the value of Bard's

12:02:14 continuous improvements, generation by generation. Look at

how the fracture rate went down. .84 percent for Recovery filter. .24 percent for G2. .21 percent for G2 Express. .17 for Eclipse. Continuous improvement paid off.

And what does that mean? That means that over 99 percent of Eclipse filters have had no reported fractures, no reported migrations, and no reported tilts.

Ladies and gentlemen, on the issue of design, when all of the evidence and argument is said and done and you deliberate, you're going to be given a verdict form. And based upon the evidence that I have just summarized, we would submit to you that on the issue of design, the evidence compels a response of no. Because the evidence demonstrates that while there is a risk with Bard filters, it is outweighed by the benefits.

Let's talk briefly about the warning defect allegation.

This is what the Court is going to instruct you about. And, ladies and gentlemen, this is a very important principle, I ask you to keep in mind, and look at the instructions if you have any questions.

Under the law, the manufacturer's duty, Bard's duty, is not to warn Mrs. Jones directly, but to warn the doctor of the risk. And why is that, you might ask? Doesn't the patient have the right? Bard is not authorized, licensed, or able to practice medicine. Doctors practice medicine. Bard

12:04:17 provides doctors with tools, or some tools, to assist them.

Bard can only tell the doctor of the risks, and it is up to that doctor to then talk to the patient. But the law is clear that the manufacturers duty to warn goes to the doctor, 12:04:34 not to the patient.

You have seen the instructions for use that come with every single device. That is Exhibit 8325.

These instructions warn about movement or migration of the filter. And caudal migration. They warn about filter 12:05:06 fractures and that they can cause serious pulmonary and cardiac complications. The instructions warn about perforation. They warn about tilt. And, importantly, they warn doctors that all of these complications can lead to medical -- the need for medical intervention or death.

12:05:32 And they counsel doctors to apply a risk/benefit ratio in determining whether any particular patient needs a filter.

And they also remind doctors of the SIR guidelines to monitor these patients, just like the FDA talked about in the 12:05:50 public health notification, doctors need to monitor these patients.

Bard also produced a brochure which it gave to doctors, giving doctors the option to give that to patients if the doctor wanted to. And that brochure that Bard furnished 12:06:11 specifically warned about the risk of fracture.

12:06:17 Bard submitted that brochure to the FDA for the FDA to review. Again, complying with regulations. Safety and nonsafety regulations.

And the FDA cleared that submission, giving Bard the 12:06:35 right to go and sell -- I mean distribute those brochures to doctors for their use if they wanted to.

Now, the plaintiffs come back and say, oh, you should have put comparative warnings in your -- comparative data in your IFU. You should have said that Bard's filters fracture X 12:06:58 amount of times versus Cook's fracturing Y amount of times.

But where is that data coming from? The evidence is that in the real world, the only source of such data is the MAUDE database maintained by the FDA, and that it is neither -- is not intended to be used for the purpose the 12:07:21 plaintiffs are claiming we should use it. That's the real world.

The evidence is also that no other manufacturer uses that data in their IFUs for IVC filters. And no doctor, as conceded by the plaintiff's own experts, even in this bubble, 12:07:45 no doctor has ever seen comparative rates for IVC filters listed in an IFU.

And, ladies and gentlemen, based upon that evidence, based upon our duty to warn the doctors, we submit to you that once you retire to the jury room, the evidence compels a note 12:08:10 to the question of failure to warn. And there will be two

12:08:15 questions on failure to warn. We submit the answer to both should be no.

Let's talk very briefly about causation.

We've mentioned earlier the plaintiff's symptoms. 12:08:31 Her principal complaint is fatigue, which she has been diagnosed with long before she had the filter implanted, long before the filter fractured, and long before the filter was removed because she suffers from anemia related to her gastric bleeding.

12:08:54 Importantly, while the doctors hired by the plaintiff's attorney came in here and tried to attribute symptoms to her filter, not a single treating doctor associates those symptoms, any symptoms, with the filter or a strut.

12:09:14 Well, they say, there's this risk of future complications and she needs medical intervention because of that risk. A risk that her doctor, her own treating doctor, said she did not have. Even her paid expert says it is only a 1 percent chance of future complications.

12:09:38 And the only study out there is a study conducted by the witness you saw testify by deposition yesterday, Dr. Scott Trerotola, and his group at the University of Pennsylvania. They evaluated 65 patients with fractured filters, and they concluded that retained fragments present little risk of late 12:10:03 complications or symptoms. That is the only study in the

12:10:06 medical literature dealing with retained struts in the pulmonary artery.

And regarding that risk, they concluded there are no reports in the medical literature of clinically significant 12:10:21 consequences. It's thought to be an asymptomatic event that is clinically insignificant. That is the only medical literature out there addressing what's going on with Mrs. Jones.

And also on the issue of causation, ladies and 12:10:37 gentlemen, is the question of warning. There is no evidence on this record that the warnings given by Bard in any way were a cause of anything that happened to Mrs. Jones.

Finally, let's talk about damages. And, ladies and gentlemen, representing Bard as I do and believing in this 12:11:06 case, I hate to mention damages because I believe so strongly, based upon the evidence you have been given, that you should never reach the question of damages, because I believe that there is no -- not evidence of a design defect and there is not evidence of an inadequate warning.

12:11:22 But if you do, for some reason, reach damages, I ask that you keep a couple of principles in mind.

First of all, the law seeks to ensure that damages awarded are fair to both parties. Fair to both parties. Reasonable.

12:11:46 In assessing damages, I ask that you keep in mind the

following. I'm not going to suggest a number because I don't believe that the evidence warrants any damage award. But if you get there, I ask you to keep in mind she has had no medical treatment since 2016. And no medical treatment related to the filter since it was removed in 2015.

No symptoms related to the fractured filter, according to her doctor. Her doctor called it an incidental finding.

No symptoms associated with the strut, according to her doctor. And virtually no risk of future complications. Only 1 percent, according to her expert, and according to the only published medical literature, simply no clinically significant risk.

Let's talk briefly about punitive damages. On the issue of punitive damages, a different burden applies.

You do not reach punitive damages or make a finding of punitive damages unless the plaintiff satisfies a very exacting standard. It's not by a preponderance of the evidence, it's clear and convincing evidence. It is a different and higher burden of proof. And the plaintiffs have to show egregious conduct on behalf of Bard by that clear and convincing evidence.

From my perspective, ladies and gentlemen, the best evidence on that issue are the men and women of Bard.

Contrary to what Mr. O'Connor said, these are not

12:13:30 suits. I would have given anything if I could have convinced some of them to wear ties into court. They just don't do that. But these are dedicated professionals. They're not suits. They're engineers. Biomedical engineers, regulatory 12:13:43 specialists, biology majors. The list goes on and on. These are men and women of this community who go to work every day trying to build a better mouse trap. Who have built six generations of retrievable filters, a revolutionary device, in 15 years time. Whose company has devoted more than 12:14:08 $18 million in development costs to do so.

I would submit to you, ladies and gentlemen, that that is not the sort of egregious behavior, and certainly not by clear and convincing evidence, to warrant the punitive damage award that the plaintiff is asking you to give.

12:14:25 And, therefore, at the end of the day, if you ever reach that question, which you won't unless you find a defect, we would respectfully submit that the evidence compels an answer of no.

Ladies and gentlemen, we are fast approaching, very 12:14:41 fast, the time that all jurors look forward to, the time that the lawyers have to sit down and shut up. And my time is coming and I'm getting ready to do so.

The plaintiff has the last word. They get to come up and make a short rebuttal argument because they have the 12:14:59 burden of proof. And, ladies and gentlemen, my hands are tied

12:15:03 when they do so. I cannot get up here and say another thing.

Mr. O'Connor can stand up, or whoever his designee is, and say whatever he wants, and I can't say a thing. My hands are tied. And it is the most frustrating few minutes of 12:15:22 a trial for me.

But I would ask you, as you hear whatever Mr. O'Connor says, and he may say anything knowing I can't rebut it, to remember the whole story, to remember what I have told you, to remember what the tests show, to remember what 12:15:40 the FDA has concluded, to remember that evidence.

Ladies and gentlemen, I recognize this is a hard case. We all want life to be risk free. Every time we put our children on the school bus, we want life to be risk free. Every time I handed my teenagers the keys to the car, I prayed 12:16:03 that their drive would be risk free. Every time we get on an airplane, we pray that it is going to be risk free. But, unfortunately, that's just not the real world.

And no matter how hard the engineers and the men and women at Bard try, they have yet to find the way to make an 12:16:27 IVC filter that is 100 percent risk free. They have gone through six generations, and every step of the way they have made the risks less and less.

No other manufacturer has found a way to make these devices risk free. But as the FDA and the medical community 12:16:50 recognizes, despite those risks, these devices are needed.

12:16:56 In the real world, ladies and gentlemen, and not in the litigation bubble, the evidence demonstrates that the benefits of these devices are necessary, and the risks, while present, are outweighed by those benefits.

12:17:16 The real world data shows how low the risk has gotten over the years.

In the real world, where we all live, you can use your common sense. You can look at the people at Bard. You can look at the documents. You can see that the FDA believes 12:17:38 that the benefits outweigh the risks of these devices. You can see that the SIR believes that. And you can see what Bard has strived to do to make the best possible filter it can.

And, so, ladies and gentlemen, as I sit down with my hands tied, I ask you to go back to the jury room and use your 12:17:57 common sense. Don't put your humanity at the side. We're all -- we all do feel sympathy for Ms. Jones. But the task ahead is to look at the evidence, where you have been charged to treat a corporation equal to an individual. And remember that this corporation is not just a monolithic entity, it is 12:18:22 the men and women you met.

And based upon all of that evidence, we would ask that, respectfully, that you return a verdict in favor of my client, Bard.

Thank you.

12:18:35 THE COURT: All right. Thank you, Mr. North.

12:18:36 Mr. O'Connor, your rebuttal.

MR. O'CONNOR: Yes, Your Honor. Thank you.

THE COURT: Everybody stand up for just a minute.

MR. O'CONNOR: Thank you, Your Honor.

12:20:05 Bard and Mr. North, they don't want to talk about the Recovery, they don't want to talk about the G2 or the G2X. As a matter of fact, they didn't even have much to say about the Eclipse and the failures and how severe they are. And they don't want to talk about them because they are inconvenient

12:20:31 truths. Because if you take the Recovery and do what should have been done here, take it out and don't sell it, the Eclipse never comes on the market.

The Eclipse, the fake out -- and let me tell you something, when the defense counsel talks about a litigation

12:20:49 bubble and talks about the lawyers representing this plaintiff and the experts we've retained, let's think about what the real world is, and its right here, right here in this courtroom, right here in this house of justice where no matter where you come from, no matter what your age, no matter what

12:21:14 your color, no matter what your gender, you come here on equal footing.

And I for one, and these lawyers that I work with, we are proud of this system and we are proud of what we do. And if anybody wants to talk about litigation, the defense thought

12:21:39 they could fake the public out with the Eclipse and they

12:21:42 thought it would be cheaper to come here and defend these cases than do the right thing and stop the harm.

Think about it. Dr. Briant loves science. Why, when you pay his company 650,000, don't you tap into that talent 12:22:03 and have him fix the filter? He just came -- and I don't even think he liked to criticize Dr. McMeeking, who came here with solutions.

Dr. Feigal, part of the $1.1 million, why didn't Bard say please help us with these comparative rates because we 12:22:19 know there's so many out there, what should we do? Why didn't they consult with the people in the real world and say, here's what do you.

In 2010 when the FDA warning letter comes out and Mr. Van Vleet sends that letter following it saying, hey, you 12:22:37 might want to think about getting these out, you tell them the truth. Tell them at Bard we know how serious our complications are. We know they're out there, and we know there's patients out there who may be walking around. And what you should be doing is getting ahold of your patients, 12:22:52 just like Dr. Asch asked, and get them in and monitor them. And they refused to do it. And they won't do it until you tell them to do it.

I think it's interesting that Dr. Asch, who was on their side, who all the way to 2003 still thought he was on 12:23:12 their side and wanted the retrievable filters to be on the

12:23:15 market, that now they take a swing on him because after 2003 he learned the truth, the truth you've learned here.

And they didn't dispute what Dr. Asch said. He heard on the streets how horrible the Recovery filter was. He 12:23:30 suspected that if they continued to do this, they were going to develop more and more filters that would hurt people, and that was after 2003 and he didn't hear from Bard.

But you know what's interesting? The one thing Dr. Asch did say. And think about this for a second. He told 12:23:45 you how he was betrayed.

And you heard from Mr. Carr, you heard from other Bard witnesses, and not one of them came in and disputed, not one of them came in here and said, we did not betray Dr. Asch.

So Bard doesn't want to talk about their tests. They 12:24:09 want to show you a lot of tests. But what they don't want to do is talk about the tests that Mr. Chanduszko confirmed are result oriented, that sometimes the G2 does better than others, depending what filter you want to get on the market. You may recall that testimony.

12:24:26 I would suggest that when you go back you look at Exhibit 854. 854, where Bard's own document shows a comparative rate between the Recovery and the G2, it shows how bad the G2 is. And remember, the G2 is the Eclipse.

Now, we heard from Dr. Grassi about the SIR 12:24:53 guidelines, and he said crystal clearly you do not use those

12:24:57 guidelines for acceptable rates, and yet that's what Bard tries to do. As soon as Dr. Grassi leaves this courtroom, Bard turns around in this courtroom and reengineers everything and uses those very guidelines to somehow convince people on 12:25:14 this jury that they have somehow complied with what is regarded as an acceptable rate, when Dr. Grassi said that was never the intention.

Let me show you some testimony real quick on the FDA.

Dr. Feigal, you remember him, he was the 12:25:47 epidemiologist. And their own expert came in here, in the real world, the courtroom, this house of justice, and told us the truth. He was asked by Mr. Lopez, do you think it will be a little misleading if someone were to say the other -- that the data proves that 99 percent of the time our device does 12:26:09 not migrate?

And he said, I think that was the data based -- if that was the data based on reports, I think that would be misleading.

Dr. Tillman, the regulatory expert, she came in here 12:26:42 and told us some pretty insightful facts about the FDA. Taken together, these shortcomings, she was asked by Mr. Lopez, of both premarket and postmarket activities raise serious concerns about FDA's regulation of medical devices, and she said yes, that is GOAO's conclusions. And Bard knows that.

12:27:06 Bard knows FDA is under-resourced. Bard knows that

12:27:07 the FDA is understaffed. Bard knows that in addition to its applications the FDA is receiving thousands. That's why it's an honor system. But that's also why we have juries. Because for all of the documents that they claim we cherry-picked, 12:27:26 they didn't come in here and show you one document that they have that would refute what we said the documents said.

Now, we did not write those documents. We can't make this stuff up.

When Dr. Ciavarella, their medical director, said, 12:27:42 why aren't doctors using the G2 -- I mean, excuse me, the Simon Nitinol instead of the G2, well, that was an important question because he knew the G2 was failing.

And we need to wonder ourselves what happens behind closed doors when you have Dr. Ciavarella asking that 12:28:00 question, and then he learns that to get rid of the baggage, they're going to disguise the G2 and call it the Eclipse to keep their hold on the market.

Think about this for a second.

If they would have done the right thing and stopped 12:28:21 it and used the technology that they knew back in 2006 and just told the public, we're going to get it out there, but we don't want to hurt any more people. Because when they're hurting people, and if they just hurt one, and they knew that their filter was capable of severe damage because of its 12:28:45 design defect, that's one too many. But, you see, Bard's not

12:28:51 going to stop.

And, you know, the FDA gave them a warning letter and caught them calling a serious injury of the Eclipse that caused the cardiac injury, calling it a malfunction, and they 12:29:10 got caught.

But who knows what they're doing now. Because the FDA is under-resourced and they have to rely on honesty.

But that's why there's an Arizona jury. Because juries can do what agencies can't, and that's find the truth, 12:29:34 learn the truth, and make sure companies get the message that in Arizona this behavior is not tolerated.

Gay, let's play Dr. Altonaga's video.

Remember Dr. Altonaga, he was another medical director at Bard.

12:30:11 (Video testimony of Dr. Altonaga played.)

MR. O'CONNOR: All right. Now, Dr. Altonaga also said in his testimony, you'll recall, that there comes a point where you don't sell it.

Now, here's the thing. They want to talk about 12:30:47 rates. They want to talk about numbers. They want to talk about a litigation bubble. But maybe they should use that $1.1 million to protect people. And since they won't, you need to help them.

There are people like Doris out there. And they 12:31:09 don't want to know their names; they like numbers. Because,

12:31:11 you see, when you refer to somebody as a number, you don't have to look at them in the eye. When you don't talk to a human being with their name, it dehumanizes them.

Well, her name is Doris Jones. And Bard knew that 12:31:31 they had put the fake out, the Eclipse, out there, that it was going to harm people. And Bard knows that there are still people out there with the Recovery, there are still people out there with the G2, there are still people out there with the G2X and the Eclipse who likely have failed filters and don't 12:31:51 know it.

And they won't stop it. So let's remind Bard that people have names. And the only way to do that is let the board of directors know that you heard Doris Jones' case and it's time to stop.

12:32:16 Thank you.

THE COURT: All right. Thank you, Mr. O'Connor.

Ladies and gentlemen, the next step is to swear two bailiffs before we discharge you. Nancy should be walking in the door right about now.

12:32:36 All right. Would you please raise your hand.

(The bailiffs were sworn.)

THE COURT: All right. Ladies and gentlemen, you can take your notes and they'll take you back to the jury room. We will get the evidence back to you along with the 12:33:12 instructions. And you are excused to deliberate.

12:33:15 Thank you.

(The jury exited the courtroom at 12:33.)

THE COURT: All right. Counsel, two things.

Please be sure to leave Traci with a way to get in touch with you if we get a question or a verdict.

12:33:43 And I would also like to get the lawyers back here at 2 o'clock to talk about the schedule for the next trial. We've got the time -- the date set in September, but I want you to -- I can't even remember if we have a summary judgment motion for the next bellwether.

12:34:02 It's waiting?

We need to deal with that, obviously.

But we need to figure out what the deadlines should be for motions in limine, for the final pretrial order. If you want to have another day like we did on April 13th where we talk about what, if anything, should be changed for the next trial, we can schedule that. But I'd like to get that schedule in place so that after we get the verdict, we know what's happening in the next case.

12:34:30 So if you could be back here at 2 o'clock, we'll discuss those issues.

Okay. Thank you.

(Recess taken from 12:34 to 12:06. Proceedings resumed in open court outside the presence of the jury.)

14:07:16 THE COURT: Please be seated.

14:07:27 All right, Counsel, I was just handed a note from the jury which says, "Please print out a hard copy exhibit list." Signed Juror 7.

Do we have such a thing?

14:07:44 (The Court and the courtroom deputy confer.)

MR. ROGERS: We should have one, Your Honor.

THE COURT: Counsel, hold on just a minute.

So this is printed off of the JERS system?

THE COURTROOM DEPUTY: It is.

14:08:12 THE COURT: So we've got one that's already printed out.

Traci, would it just be these pages?

(The Court and the courtroom deputy confer.)

THE COURT: Could you show them and see if they can

14:08:29 agree.

She'll print it. This is one that prints off of the system, so that might be the easiest way. It shows whether the exhibits are plaintiff or defense exhibits. I'm assuming that doesn't matter.

14:08:45 Okay. We'll have Traci print it and then we can look at it.

MR. O'CONNOR: It just shows admitted ones; right?

THE COURT: Yeah, the ones that are on the system.

(Scheduling conference discussion regarding next

14:09:04 bellwether reported but not transcribed herein.)

14:11:01 THE COURTROOM DEPUTY: I'll show them the exhibit list.

THE COURT: Okay.

So does that look okay?

14:11:52 MR. O'CONNOR: Yes.

THE COURT: Okay. Traci, let's just put a note in the docket and take that back to them.

THE COURTROOM DEPUTY: Okay.

THE COURT: All right.

(End of transcript.)

* * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 1st day of June, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter